MINUTES OF 335 TH MEETING OF REGISTRATION BOARD HELD ON 25 TH APRIL, 2024

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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<	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 $334^{\rm th}$ 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	M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2,
1.	/ Applicant	National industrial zone, RCCI Estate Rawat-Islamabad
	Brand Name +Dosage Form +	DT-NIX Water Soluble Powder
	Strength	D1-MX water Soluble I owder
	Composition	Each 100 gm contains.
	Composition	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	M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2,
	/ Applicant	National industrial zone, RCCI Estate Rawat- Islamabad
	Brand Name +Dosage Form +	TDBC-NIX PLUS ORAL Powder
	Strength	
	Composition	Each Kg contains.
		Doxycycline HCl 400 gm
		Tylosin Tartrate200 gm
		Colistin Sulphate 500MIU
		Bromhexine HC110gm
	Tracking ID/Date of submission & fee	Bromhexine HCl10gm Tracking ID: 7YR-X6T-QUM4 dated 20-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	Bromhexine HCl10gm Tracking ID: 7YR-X6T-QUM4 dated 20-03-2024, Rs. 30,000/- 07-03-2024 Antibiotic/Mucolytic
	Pharmacological Group Type of Form	Bromhexine HCl10gm Tracking ID: 7YR-X6T-QUM4 dated 20-03-2024, Rs. 30,000/- 07-03-2024 Antibiotic/Mucolytic Form 5
	Pharmacological Group Type of Form Finished Product Specification	Bromhexine HCl10gm Tracking ID: 7YR-X6T-QUM4 dated 20-03-2024, Rs. 30,000/- 07-03-2024 Antibiotic/Mucolytic Form 5 As per Innovator's specifications
	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price	Bromhexine HCl10gm Tracking ID: 7YR-X6T-QUM4 dated 20-03-2024, Rs. 30,000/- 07-03-2024 Antibiotic/Mucolytic Form 5
	Pharmacological Group Type of Form Finished Product Specification	Bromhexine HCl10gm Tracking ID: 7YR-X6T-QUM4 dated 20-03-2024, Rs. 30,000/- 07-03-2024 Antibiotic/Mucolytic Form 5 As per Innovator's specifications 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in	Bromhexine HCl10gm Tracking ID: 7YR-X6T-QUM4 dated 20-03-2024, Rs. 30,000/- 07-03-2024 Antibiotic/Mucolytic Form 5 As per Innovator's specifications 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg,
	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities.	Bromhexine HCl10gm Tracking ID: 7YR-X6T-QUM4 dated 20-03-2024, Rs. 30,000/- 07-03-2024 Antibiotic/Mucolytic Form 5 As per Innovator's specifications 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status	Bromhexine HCl10gm Tracking ID: 7YR-X6T-QUM4 dated 20-03-2024, Rs. 30,000/- 07-03-2024 Antibiotic/Mucolytic Form 5 As per Innovator's specifications 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg Broxtin 24 Oral Powder of M/s Leads (Reg. # 088045)
	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status	Bromhexine HCl10gm Tracking ID: 7YR-X6T-QUM4 dated 20-03-2024, Rs. 30,000/- 07-03-2024 Antibiotic/Mucolytic Form 5 As per Innovator's specifications 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg Broxtin 24 Oral Powder of M/s Leads (Reg. # 088045)

	/ Applicant	National industrial zone, RCCI Estate Rawat- Islamabad
	Brand Name +Dosage Form +	TDBC-NIX ORAL Powder
	Strength	
	Composition	Each 100gm contains.
		Doxycycline HCl 40 gm
		Tylosin Tartrate20 gm
		Colistin Sulphate 10gm
		Bromhexine HCl2gm
	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	Ç
	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.	
	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 +	NIX GOLD Oral Powder
	Strength	
	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 B21.25 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.
	6	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.	
5.	Decision: Approved. Name and address of manufacturer	M/a Dharmanir Dharmacarticala plat # 29 St # SS 2
5.	/ Applicant	M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat-Islamabad
	Brand Name +Dosage Form +	ACO NIX-40 Oral Powder
	Strength	ACO MA-40 Oral I owder
	Composition	Each 1000 gram contains
	Composition	Lincomycin as HCl 400 gm
	Tracking ID/Date of submission & fee	Tracking ID: A7E-R4D-Q5GM dated 19-03-2024, Rs.
	Tracking 12/2 are of such assisting to rec	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,
	r	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	M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2,
	/ Applicant	National industrial zone, RCCI Estate Rawat-Islamabad
	Brand Name +Dosage Form +	ACO NIX-11 Oral Powder
	Strength	
	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 +	NEO NIX- 72 Oral Powder
	Strength	
	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	M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2,
	/ Applicant	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	M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2,
	/ Applicant	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.	1100 2112 155000 511 25 01 252 11
	Decision: Approved.	
11.	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 +	COLI-48 Oral Powder
	Strength	0021 10 014110 11401
	Composition	Each gram contains:
	Composition	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.	1,000 2,000 30 23 37 232 10
	Decision: Approved.	
12.	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 +	COLI-6 Oral Powder
	Strength	
	Composition	Each Gram Contains:
		Colistin Sulphate 6 MIU
	Tracking ID/Date of submission & fee	T1 ID- 700 TTC 2011 1-4-114 02 2024 D-
		Tracking ID: ZQG-TTS-361J dated 14-03-2024, Rs. 30,000/- 07-03-2024
	Pharmacological Group	
		30,000/- 07-03-2024
	Pharmacological Group	30,000/- 07-03-2024 Antibiotic
	Pharmacological Group Type of Form	30,000/- 07-03-2024 Antibiotic Form 5
	Pharmacological Group Type of Form Finished Product Specification	30,000/- 07-03-2024 Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg,
	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price	30,000/- 07-03-2024 Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg,
	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in	30,000/- 07-03-2024 Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg,
	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities.	30,000/- 07-03-2024 Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg
	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status	30,000/- 07-03-2024 Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg Acme Col -60 Water Soluble Powder (Reg. # 116967)
	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status	30,000/- 07-03-2024 Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg Acme Col -60 Water Soluble Powder (Reg. # 116967)
13.	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator.	30,000/- 07-03-2024 Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg Acme Col -60 Water Soluble Powder (Reg. # 116967)
13.	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator. Decision: Approved.	30,000/- 07-03-2024 Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg Acme Col -60 Water Soluble Powder (Reg. # 116967) New DML issued on 26-01-2024.
13.	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator. Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	30,000/- 07-03-2024 Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg Acme Col -60 Water Soluble Powder (Reg. # 116967) New DML issued on 26-01-2024. M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2,
13.	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator. Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	30,000/- 07-03-2024 Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg Acme Col -60 Water Soluble Powder (Reg. # 116967) New DML issued on 26-01-2024. M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad V.VIT NIX Oral Powder
13.	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator. Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	30,000/- 07-03-2024 Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg Acme Col -60 Water Soluble Powder (Reg. # 116967) New DML issued on 26-01-2024. M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad V.VIT NIX Oral Powder Each gram contains:
13.	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator. Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg Acme Col -60 Water Soluble Powder (Reg. # 116967) New DML issued on 26-01-2024. M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad V.VIT NIX Oral Powder Each gram contains: Vitamin E
13.	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator. Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg Acme Col -60 Water Soluble Powder (Reg. # 116967) New DML issued on 26-01-2024. M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad V.VIT NIX Oral Powder Each gram contains: Vitamin E
13.	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator. Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg Acme Col -60 Water Soluble Powder (Reg. # 116967) New DML issued on 26-01-2024. M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad V.VIT NIX Oral Powder Each gram contains: Vitamin E
13.	Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator. Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Antibiotic Form 5 As per Innovator's specifications. 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 25Kg Acme Col -60 Water Soluble Powder (Reg. # 116967) New DML issued on 26-01-2024. M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2, National industrial zone, RCCI Estate Rawat- Islamabad V.VIT NIX Oral Powder Each gram contains: Vitamin E

		Virginiamycin12mg
	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.
	•	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg,
	Pack size & demanded price	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	M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2,
	/ Applicant	National industrial zone, RCCI Estate Rawat-Islamabad
	Brand Name +Dosage Form +	CNO SUPER Oral Powder
	Strength	CIVO SCI EK GIAI I GWACI
	Composition	Each gram contains:
	Composition	Oxytetracycline HCl 300mg
		Neomycin Sulphate 250mg
		Colistin Sulphate 250Hg
	Treating ID/Data of submission & fac	
	Tracking ID/Date of submission & fee	Tracking ID: BH4-REM-6NT6 dated 13-03-2024, Rs.
	N 1 1 1 C	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.	THE METAL ISSUED OF EOUT 20211
	Decision: Approved.	
15.	Name and address of manufacturer	M/s Pharmonix Pharmaceuticals plot # 28 St.# SS- 2,
13.	/ Applicant	National industrial zone, RCCI Estate Rawat-Islamabad
	Brand Name +Dosage Form +	CNO COLI PLUS Oral Powder
	_	CNO COLLI LOS OTALI OWUEL
	Strength Composition	Fach grow contains:
	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	<i>U</i>
	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	M/s Hirra Pharmaceutical Laboratories (Private)
	/ Applicant	Limited
		1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.
		(DML # 000449)
	Brand Name +Dosage Form +	HIRRA-AMPRO-98 Oral Water Soluble Powder
	Strength	
	Composition	Each gm contains:
		Amprolium HCl980mg
	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	M/s Hirra Pharmaceutical Laboratories (Private)
	/ Applicant	Limited
		1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.
	D IN D E	(DML # 000449)
	Brand Name +Dosage Form +	Hirra-Doxy.T.D.C.B powder
	Strength Composition	Each 100gm contains:
	Composition	Doxycycline HCl 20gm
		Tylosin tartrate 10gm
		Bromohexine0.4gm
		Colistin sulphate45MIU
	Tracking ID/Date of submission & fee	Tracking ID: TZE-ETU-ESRS dated 04-04-2024, Rs.
	Tracking ib/bate of submission & rec	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.
	Pack size & demanded price	1000gm, 500gm, 100gm, 50gm.

		T
	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.
	D 1M D E	(DML # 000449)
	Brand Name +Dosage Form + Strength	HIRRA-LINCOSPEC PLUS POWDER
	Composition	Each Gram contains:
		Lincomycin as HCl33.3%w/w
		Spectinomycin as sulphate66.7% 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	<u> </u>
	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 +	HIRRA-LINCOSPEC ORAL POWDER
	Strength	
	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	0, 0, - 00,0, 000, 000, 000,
	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.	1
20.	Name and address of manufacturer	M/s Hirra Pharmaceutical Laboratories (Private)
•	/ Applicant	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:
	Composition	Lincomycin HCl Monohydrate44gm
	Tracking ID/Date of submission % for	
	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	1005, 2005, 5005, 185, 585, 1085, 2385
	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	M/s Hirra Pharmaceutical Laboratories (Private)
	/ Applicant	Limited 1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)
	Brand Name +Dosage Form +	HIRRA-LINCOCYN-11% Oral powder
	Strength	
	Composition	Each 100 Gram contains:
		Lincomycin HCl Monohydrate11gm
	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
	C) (D)	PHARMACEUTICALS (Reg. # 102212)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
	Decision: Approved.	T
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 +	HIRRA-LINCOCOL ORAL POWDER
	Strength	Food 100Cram contains:
	Composition	Each 100Gram contains:
		Lincomycin as HCl10gm
	Trocking ID/Data of automician 0.6	Colistin sulphate80MIU
	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	<u> </u>
	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.	Thew Divid (ullesil) issued on 10 of 2024.
	Decision: Approved.	
23.	Name and address of manufacturer	M/s Hirra Pharmaceutical Laboratories (Private)
25.	/ Applicant	Limited
	/ Applicant	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.
		(DML # 000449)
	Brand Name +Dosage Form +	HIRRA-HEXA FLUSH WATER SOLUBLE
	Strength	POWDER
	Composition	Each gm Contains:
	Composition	Hexamethylene tetramine 955mg
		Vitamin B2 10mg
		Calcium pantothenate 5mg
		Nicotinamide25mg
	Tracking ID/Date of submission & fee	Tracking ID: PBW-LVB-J2UQ dated 04-04-2024, Rs.
	Tracking 15/15 are of submission & rec	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	100gm ,500gm,1000gm
	Reference Regulatory Authorities.	
	Me-too status	FILTRAX WATER SOLUBLE POWDER of M/s PRIX
	We-too status	Pharmaceutical (Reg. # 043289)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	Thew BinE (directly issued on 10 of 2021.
	Decision: Approved.	
24.	Name and address of manufacturer	M/s Hirra Pharmaceutical Laboratories (Private)
- "		Limited
	1 / ADDIICAIII	l Limitea
	/ Applicant	
	/ Applicant	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)
	Brand Name +Dosage Form +	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)
		1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.
	Brand Name +Dosage Form +	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449)
	Brand Name +Dosage Form + Strength	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder
	Brand Name +Dosage Form + Strength	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains:
	Brand Name +Dosage Form + Strength	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm
	Brand Name +Dosage Form + Strength Composition	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm
	Brand Name +Dosage Form + Strength	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine 05gm Colistin sulphate
	Brand Name +Dosage Form + Strength Composition	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine
	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine 05gm Colistin sulphate
	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine
	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine 05gm Colistin sulphate 480MIU Tracking ID: BWY-R8Z-RAWT dated 04-04-2024, Rs. 30,000/- 27-03-2024 Antibiotic, Mucolytic, Expectorant
	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group Type of Form	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine 05gm Colistin sulphate
	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group Type of Form Finished Product Specification	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine 05gm Colistin sulphate
	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine 05gm Colistin sulphate
	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine
	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities.	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine
	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine
	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator.	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine
	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine
25.	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator.	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine
25.	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator. Decision: Approved.	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine
25.	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator. Decision: Approved. Name and address of manufacturer	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine 05gm Colistin sulphate
25.	Brand Name +Dosage Form + Strength Composition Tracking ID/Date of submission & fee Pharmacological Group Type of Form Finished Product Specification Pack size & demanded price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator. Decision: Approved. Name and address of manufacturer	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore. (DML # 000449) Hirra-Doxy.T.C.B-300 powder Each 1000gm contains: Doxycycline HCl 200gm Tylosin tartrate 100gm Bromohexine

	T a .	T	
	Strength	F 1 100	
	Composition	Each 100gm contains:	
		Doxycycline HCl40g	
		Tylosin tartrate20g	
	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	30gm, 100gm, 300gm, 1000gm	
	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.	Thew Divid (affesti) issued off 10-01-2024.	
	Decision: Approved.		
26.	Name and address of manufacturer	M/a Hima Dhamasantial Laboratorias (Drivata)	
20.		M/s Hirra Pharmaceutical Laboratories (Private) Limited	
	/ Applicant		
		1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.	
	Prond Name + Decease Farmer	(DML # 000449) Hirra-Colistine Oral Powder	
	Brand Name +Dosage Form + Strength	Hirra-Constine Oral Powder	
	Composition	Each Kg contains	
		Colistin sulphate500MIU	
	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	
	Remarks of the Evaluation.	per Kg	
	Decision: Approved with following co		
	"Each Kg contains	F	
	Colistin sulphate5MIU"		
		/- for correction in formulation, prescribed vide S.R.O.	
	496(I)/2023 dated 17-04-2023		
27.	Name and address of manufacturer	M/s Hirra Pharmaceutical Laboratories (Private)	
	/ Applicant	Limited	
	-FF	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.	
		(DML # 000449)	
	Brand Name +Dosage Form + Strength	Hirra-Amantadine 10% Powder	
	<u> </u>	Fach 100cm contains:	
	Composition	Each 100gm contains: Amantadine HCl10gm	
	Tracking ID/Data of submission 0- for	Tracking ID: <u>T7G-UYT-NYW3</u> dated 04-04-2024, Rs.	
	Tracking ID/Date of submission & fee		
	Dhamaaalaa'1 Co	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	7 1 6 7 1 6 7 1 7 6
	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	M/s Hirra Pharmaceutical Laboratories (Private)
	/ Applicant	Limited
		1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.
		(DML # 000449)
	Brand Name +Dosage Form +	Hirra Dox 80% Powder
	Strength	
	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	M/s Hirra Pharmaceutical Laboratories (Private)
	/ Applicant	Limited
		1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.
		(DML # 000449)
	Brand Name +Dosage Form +	HIRRA-ENRO-10% ORAL SOLUTION
	Strength	
	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.	Decision: Approved. Name and address of manufacturer	M/s Hirra Pharmaceutical Laboratories (Private)
30.	Decision: Approved.	M/s Hirra Pharmaceutical Laboratories (Private) Limited 1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.

		(DML # 000449)
	Brand Name +Dosage Form +	Hirra-Tilcos 25% Oral Solution
	Strength	
	Composition	Each ml contains
		Tilmicosin Phosphate250mg
	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	M/s Hirra Pharmaceutical Laboratories (Private)
	/ Applicant	Limited
		1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.
		(DML # 000449)
	Brand Name +Dosage Form +	Hirra-Suppliment Oral Solution
	Strength	
	Composition	Each ml contains
		Calcium-Chloride-Hexahydrate2mg
		Magnesium-Chloride Hexahydrate4mg
		Potassium-Chloride8mg
		Sodium-Chloride120mg
		Cyanocobalamin0.025mg Sodium-Lactate42.7mg
	Tracking ID/Date of submission & fee	Č
	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	M/s Hirra Pharmaceutical Laboratories (Private)
	/ Applicant	Limited
		1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.
		(DML # 000449)
	Brand Name +Dosage Form +	Hirra-S.Nor.C Oral Liquid
	Strength	
	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.
	N. 1 : 1G	30,000/- 27-03-2024
i	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Type of Form	
	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.	THE WELL CONTROL OF THE OF THE THE
	Decision: Approved.	
33.	Name and address of manufacturer	M/a Hinna Dhammacautical Laboratorica (Driveta)
33.		M/s Hirra Pharmaceutical Laboratories (Private) Limited
	/ Applicant	1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.
	D IV D E	(DML # 000449)
	Brand Name +Dosage Form + Strength	Hirra Oxyfenda Gold Oral Liquid
	Composition	Each ml Contains:
	•	Oxyclozanide 62mg
		Oxfendazole22.65mg
		Selenium0.5mg
		Cobalt as sulphate1.67mg
	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	M/s Hirra Pharmaceutical Laboratories (Private)
	/ Applicant	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.	(1. 1.1.) 1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.
	Decision: Approved.	
	Decision, Approved.	

35.	Name and address of manufacturer / Applicant	M/s Hirra Pharmaceutical Laboratories (Private) Limited
	/ Applicant	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
	Tracking ID/Date of submission & fee	Colistin Sulphate 50MIU 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
	, rippicant	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,
	1.10 000 00000	M/S.HAAROLDS PHARMACEUTICALS(PVT) LTD
		(Reg. # 109074)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	(1200)
	Decision: Approved.	
38.	Name and address of manufacturer	M/s Hirra Pharmaceutical Laboratories (Private)
	/ Applicant	Limited
		1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.
		(DML # 000449)
	Brand Name +Dosage Form +	Hirra-Bvendaclose Plus Oral Suspension
	Strength	•
	Composition	Each ml contains:
		Albendazole 100mg
		Closantel20mg
	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	M/s Hirra Pharmaceutical Laboratories (Private)
	/ Applicant	Limited
		1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.
		(DML # 000449)
	Brand Name +Dosage Form +	Hirra-Abizole Plus Drench
	Strength	
	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.
	G) E)	# 101455)
	GMP status	New DML (afresh) issued on 16-01-2024.
	Remarks of the Evaluator.	
46	Decision: Approved.	Table 22
40.	Name and address of manufacturer	M/s Hirra Pharmaceutical Laboratories (Private)
	/ Applicant	Limited
		1.3 km (Asil Raiwind Road, Ladhaky Bhular) Lahore.

	(DML # 000449)
Brand Name +Dosage Form +	HIRRA MULTI RS SOLUTION
Strength	
Composition	Each ml Contains:
	Sulphadiazine35.500mg
	Sulphadimidine28.400mg
	Neomycin Sulphate1.800mg
	Hyoscine Methylbromide 0.040mg
	Pectin 7.100mg
	Kaolin103.300mg
	Vitamin B10.150mg
	Vitamin B20.220mg
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 PHARMACEUTICA
	(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 sodium2g Tazobactam as sodium0.25g
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.
E I & I DEC	

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	☐ 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months. Sitagliptin: Firm has submitted stability study data of 3 batches of drug substance at both condensed as well as real time conditions. The	
	1	substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 18 months.		
Module-III Drug Pr	I I S	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
Pharmaceutical Eq Comparative Dissol	lution Profile a	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/verificati		Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
varidation/verificati		ABILITY STUDY DATA		
Address: No. Inner Mongoli: Sitagliptin Ph Name: Zhejiar Address: No.		g Arker Pharmaceutical Technology Co., Ltd. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, a, China. osphate Monohydrate: ng Yongtai Pharmaceutical Co., Ltd 1, 4th Donghai Avenue, Zhejiang Provincial Chemical and Medical Base Linhai Zone, Linhai City, Zhejiang Province, 317016, China.		
API Lot No.	Ertugliflozin: 182			
Description of Pack (Container closure system)	Alu alu Plictor			
Stability Storage Condition	Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No. T01			T02	T03
Batch Size	1500 Table	et	1500 Tablet	1500 Tablet
Manufacturing Date	06-2021		06-2021	06-2021
Date of Initiation	21-06-2021	1	21-06-2021	21-06-2021
No. of Batches			03	
DOCUMENTS / D	ATA TO BE PR	OVID	ED ALONG WITH STA	ABILITY STUDY DATA

applications with stability study data of the firm (if any)	product meeting points: i. ii.	s approval of applications with stability study data of our Tanavul Tablets 10mg which was approved in 320 th of Registration Board. The report confirms following The HPLC software is 21CFR compliant. Firm has demonstrated audit trail reports of testing.
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		
	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.	
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 HP system along with audit trail report for product testing.		
temperature and humidity humidity monitoring of stability chambers chamber		s submitted record of digital data logger for temperature and y monitoring of real time and accelerated stability rs.
ks of Evaluator:		
Manufacturer will place first three proposed shelf life and on acceleration registration application. Manufacturer will perform process.	ee produ ated stud eess vali	ction batches on long term stability studies throughout dies for six months as per the commitment submitted in dation of first three batches as per the commitment
Name, address of Applicant / Marketing Authorization Holder		M/s Caraway Pharmaceuticals Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
		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
	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. 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) ks of Evaluator: on: Approved with Innovator's specific the registration application. Manufacturer will place first three proposed shelf life and on accelerate the registration application. Manufacturer will perform proc submitted in the registration applicant / Marketing Authorization Holder Name, address of Manufacturing signals.	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. 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) ks of Evaluator: m: Approved with Innovator's specification Manufacturer will place first three produproposed shelf life and on accelerated studies the registration application. Name, address of Applicant / Marketing Authorization Holder Name, address of Manufacturing site.

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 HCl250mg
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH and the real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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,

		realidation of analystical	
		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 v of product	validation/verification	Firm has submitted ver substance and the drug pro	rification studies of the drug oduct.
Stability studies		Firm has submitted stabiliat both accelerated and lor	ity studies data of three batches ng term conditions.
,	STABILIT	Y STUDY DATA	
facturer of API			
ot No.	TH0020121		
iption of Pack niner closure system)	Alu-Alu blister pack	ed in unit carton	
ity Storage Condition			
Period	Real time: 6 months Accelerated: 6 month	hs	
ency			
No.	TE250T004	TE250T005	TE250T005 TE250T006
Size	1000 Tablet	1000 Tablet	1000 Tablet
facturing Date	05-2021	05-2021	05-2021
Batches		03	
DOCUMENTS / DAT	TA TO BE PROVIDI	ED ALONG WITH STAB	ILITY STUDY DATA
		S	N/A
Approval of API/ DML/GMP certificate of AP			
Documents for the procurement of API with approval from DRAP (in case of import).		h	
attested respective documents like		e	ubmitted
Compliance Record of HPLC software 21CFR & audit trail reports on product testing		S	ubmitted
Record of Digital data logger for temperatur			ubmitted
	Comparative Dissolut Analytical method v of product Stability studies Facturer of API ot No. ption of Pack ainer closure system) ty Storage Condition Period ency No. Size Facturing Date Batches DOCUMENTS / DAT Reference of previous apwith stability study data Approval of API/ DML/manufacturer issued by authority of country of countr	Comparative Dissolution Profile Analytical method validation/verification of product Stability studies STABILIT Facturer of API M/s Saptagir Labora Ananthasagar (Vill) of No. TH0020121 ption of Pack Alu-Alu blister pack period Period Real time: 30°C ± 2° Accelerated: 40°C ± Real time: 6 months Accelerated: 6 months Accelerated: 6 months Accelerated: 6 months Accelerated: 7, 3, 6 (Months of the Company of the Compa	Pharmaceutical Equivalence Comparative Dissolution Profile Analytical method validation/verification of product Stability studies Stability studies STABILITY STUDY DATA Firm has submitted versubstance and the drug profile at both accelerated and lor substance and the drug profile at both accelerated and lor Ananthasagar (Vill) chegunta (Mandal), Medak of No. TH0020121 ption of Pack diner closure system) ty Storage Condition Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Accelerated: 60 months Period Real time: 6 months Accelerated: 0, 3, 6 (Months) Real Time: 3, 6 (Months) No. TE250T004 TE250T005 Size 1000 Tablet 1000 Tablet 1000 Tablet 2000 Tablet 2

Remarks of Evaluator^{II}:

Section #	Observations	Firm's response
1.3	Latest GMP inspection report of the drug	
	product manufacturer shall be submitted,	
1.5.0	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		
3.2.3.4.4	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	
J.4.1 .4.4.1	mediums of pH 1.2, 4.5 & 6.8 performed against	
	the reference product.	
3.2.S.7	• Long term stability studies data for	
3.2.0.7	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:	
01212 1010	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.

DCCIS	becision. Registration board deferred the ease 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 2009-2022	
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	EachFilmCoatedtabletcontains:Empagliflozin	
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 table	
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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 24months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months Linagliptin:	

				55% ± 5%RH for 60months / 75% ± 5%RH for 6 months	
			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.		
	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 va product		accuracy, precision and	dies have submitted including specificity.	
		STABILIT	Y STUDY DATA		
Manuf	facturer of API	M/s Zhejiang Hongyuan I Zhejiang China,317016 Linagliptin: M/s Lee Pharma Limited		td Chem&APIs Industrial Zone, 58/1, Door no: 11-6/56, C- ar (Post), Hyderabad – 500 037,	
API L	ot No.	For Empagliflozin: B#EPG20220303 For Linagliptin: B# LIF22008			
	escription of Pack		ed in unit carton (3×10's)		
Stabili	ity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time l	Period	Real time: 6 months Accelerated: 6 month	ns		
Freque	ency	Accelerated: 0, 3, 6 (Months) Real Time: 3, 6 (Months)			
Batch	No.	THL001	THL002	THL003	
Batch	Size	2500 Tablet	2500 Tablet	2500 Tablet	
Manuf	facturing Date	06-2022	06-2022	06-2022	
Date of	of Initiation	19-06-2022	20-06-2022	21-06-2022	
No. of	Batches		03		
45.	Name, address of Ap Authorization Holder		M/s Wimits Pharmace	uticals (Pvt) Ltd. Lahore	
	Name, address of Manufacturing site. Status of the applicant		M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore		
				f 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	
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 Boehrin 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-PI 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 an controls, specifications, analytical procedures and it verification, batch analysis and justification of specification, reference standard, container closur system and stability studies of drug substance	

				55% ± 5%RH for 60months / 75% ± 5%RH for 6 months
	Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile		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.	
			against Glyxambi 10m Ingelheim CDP has bee brand that is Glyxam Boehringer Ingelheim in Buffer (pH-4.5) & Pho	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 va	lidation/verification of	Method validation stud accuracy, precision and	lies have submitted including specificity.
		STABILITY	Y STUDY DATA	
Manu	Zhejiang China,317010 Linagliptin: M/s Lee Pharma Lim		lited, Survey no: 257& 258/1, Door no: 11-6/56, C-ctory, Moosapet Balanagar (Post), Hyderabad – 500 037,	
API I	API Lot No. For Empagliflozin: B#EPG20220303 For Linagliptin: B# LIF22008			
	ption of Pack inner closure system) Alu-Alu blister packed in unit carton (3×10's)			
Stabi	lity Storage Condition	on Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time	Period	Real time: 6 months Accelerated: 6 month	S	
Frequ	iency	Accelerated: 0, 3, 6 (More		
Batch	n No.	THE001	THE002	THE003
Batch	n Size	2500 Tablet	2500 Tablet	2500 Tablet
Manu	ıfacturing Date	06-2022	06-2022	06-2022
Date	of Initiation	16-06-2022	17-06-2022	18-06-2022
No. o	of Batches		03	
	DOCUMENTS / DATA 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.			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: Empagliflozin5 mg Metformin HCl500mg	
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) Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile		Submitted for both drug substances as per Zone IV conditions 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 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 pro		Method validation studies have submitted including linearity, range, accuracy, precision, specificity.	
		STABILITY STUD	Y 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 Siz	ze	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 E	BE PROVIDED ALO	NG WITH STABILIT	ΓΥ STUDY DATA
1.	Reference of previous ap with stability study data		N/A	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Copy of GMP certific by Jiangsu Drug Adm till 29/11/2024. Metformin: Copy of GMP certific	ate No. 23064344 issued by Iministration Chandhinagar

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	N/A.
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.P.8.3	Submit following:	Firm has submitted 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. 	 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.

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

Per unit Pharmacotherapeutic Group of (API) Pharmaceutical form of applied drug Reference to Finished product specifications Proposed Pack size Proposed Pack size As per SRO Proposed unit price As per SRO 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-Industrial Triangle, Kahuta Road, Islamabad - Pakistan. Firm has submitted QOS as per WHO QOS-PD temph Firm has submitted QOS as per WHO QOS-PD temph Firm has submarized information related to nomenclat structure, general properties, solubilities, physical fo manufacturers, description of manufacturing process controls, specifications, analytical procedures and validation, batch analysis and justification of specifications and product. Module-III Drug Substance: Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubility physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and validation, batch analysis and justification specification specification, sandytical procedured and its validation, batch analysis and justification specification, reference standard, container closure system and stability studies of Drug Substance (Conditions & duration of Stability studies of drug substance of both AI separately. Both accelerated & long-term stability studies from I Vision Pharma has been submitted for Esomeprazole 8.5% pellets as per Zone IV a conditions. Firm has submitted data of drug product including description, composition, pharmaceutical developms manufacture, manufacturing process can description, composition, pharmaceutical developms manufacture, specifications, reference standard materials, container closure system and stability. Firm has submitted dota of drug product including description of analytical procedures, batch analy justification of specifications,	The proposed proprietary name / brand name	Gerdmax 20mg Capsule
Pharmaceutical form of applied drug Reference to Finished product specifications Proposed Pack size Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-PD templ. Firm has submitted QOS as per WHO QOS-PD templ. Firm has submitted QOS as per WHO QOS-PD templ. Firm has submitted quities, physical for manufacturers, description of manufacturing process controls, specifications, analytical procedures and validation, batch analysis and justification of specificati reference standard, container closure system and stabi studies of drug substance of both API's separately and diproduct. Module-III Drug Substance: Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubility physical form, manufacturers, description of manufacture process and controls, specifications, analytical procedures and stability studies of drug substance of both API's separately and diproduct. Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubility physical form, manufacturers, description of manufacture process and controls, specifications, analytical procedured and its validation, batch analysis and justification of specifications and stability studies of drug substance of both AI separately. Stability Studies of Drug Substance (Conditions & duration of Stability studies of drug substance of both AI separately. Both accelerated & long-term stability studies from the submitted data of drug product including description, composition, pharmaceutical developme manufacture, manufacturing process and process controduct gainst to Nexum capuale of Ms Getz. Firm has submitted pharmaceutical equivalence of the product against the Nexum capuale of Ms Getz. Firm has submitted Disvance and their product against the Nexum capuale of Ms Getz. Firm has submitted Disvance and	Active Pharmaceutical ingredient (API)	Enteric Coated Pellets of Esomeprazole Magnesium
Reference to Finished product specifications Proposed Pack size As per SRO Proposed unit price As per SRO Approved by US FDA Approved by US FDA Approved by US FDA Approved by US FDA Module-II (Quality Overall Summary) Module-II (Quality Overall Summary) Module-III Drug Substance: Module-III Drug Substance: Module-III Drug Substance: Stability Studies of Drug Substance (Conditions & duration of Stability Studies) Module-III Drug Product: Stability Studies of Drug Substance Comparative Dissolution Profile Pharmaceutical Equivalence and Comparative Dissolution Profile Pharmaceutical Equivalence and Comparative Dissolution Profile As per SRO As per SRO As per SRO Approved by US FDA Approved by US	Pharmacotherapeutic Group of (API)	Capsule
Proposed Pack size Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-PD temple Firm has submitted data of drug substance of both API's separately. Module-III Drug Substance: Module-III Drug Substance: Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubilities, physical for manufacturers, description of manufacturing process and validation, batch analysis and justification of specification specifications, analytical procedures and validation, batch analysis and justification of specifications of drug substance of both API's separately and deproduct. Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubility physical form, manufacturers, description of manufacture process and controls, specifications, analytical procedure and its validation, batch analysis and justification specification, reference standard, container closure syst and stability studies of Drug Substance (Conditions & duration of Stability validation, reference standard, container closure syst and stability studies of Drug Substance (Conditions & duration of Stability validation, patch analysis and justifications) Module-III Drug Product: Both accelerated & long-term stability studies from the separately. Stability Studies of Drug Substance (Conditions & duration of Stability validation protocols, control of excipients, control drug product, specifications, analytical procedure validation of analytical procedures, batch analy justification of specifications, reference standard materials, container closure system and stability. Firm has submitted data of drug product including description, composition, pharmaceutical equivalence of the product against the Nexum capsule of M/s Getz. Firm has submitted Drug Product against timovator's product Glyxambi Tablets 10mg/5	Pharmaceutical form of applied drug	Proton pump inhibitor
Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Module-II (Quality Overall Summary) Module-II (Quality Overall Summary) Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-PD templ. Firm has submitted properties, solubilities, physical for manufacturers, description of manufacturing process a controls, specifications, analytical procedures and validation, batch analysis and justification of specificati reference standard, container closure system and stabi studies of drug substance of both API's separately and d product. Module-III Drug Substance: Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubility physical form, manufacturers, description of manufacture process and controls, specifications, analytical procedure and its validation, batch analysis and justification specification, reference standard, container closure syst and stability studies of drug substance of both AF separately. Stability Studies of Drug Substance (Conditions & duration of Stability Studies) Module-III Drug Product: Stability Studies of Drug Substance Woodule-III Drug Product: Firm has submitted data of drug product including description, composition, pharmaceutical development manufacture, manufacture, manufacture, substance of both AF separately. Pharmaceutical Equivalence and Comparative Dissolution Profile Pharmaceutical Equivalence and Comparative Dissolution Profile Firm has submitted Dissolution Stability and submitted Dissolution Medias. Analytical method validation/verification Firm has submitted CDP results of their product against innovator's product Glyxambi Tablets 10mg/5mg in dissolution medias.		USP
The status in reference regulatory authorities For generic drugs (me-too status) Nexum 20 mg cap of M/s Getz pharma (Reg.# 033891) Name and address of API manufacturer. Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-PD temple. Firm has submitted procedures and validation, batch analysis and justification of specifications, analytical procedured and its validation, batch analysis and justification of process and controls, specifications, analytical procedured and its validation, batch analysis and justification of specifications and stability Studies of drug substance of both API's separately and deproduct. Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubility physical form, manufacturers, description of manufacture process and controls, specifications, analytical procedured and its validation, batch analysis and justification specification, reference standard, container closure syst and stability studies of drug substance of both AI separately. Stability Studies of Drug Substance (Conditions & duration of Stability studies of drug substance of both AI separately. Both accelerated & long-term stability studies from 1 Vision Pharma has been submitted for Esomeprazole 8.5% pellets as per Zone IVa conditions. Firm has submitted data of drug product including description, composition, pharmaceutical developm manufacture, manufacture, manufacturing process and process cont process validation protocols, control of excipients, control drug product, specifications, analytical procedured walidation of analytical procedures, batch analy justification of specifications, reference standard materials, container closure system and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile Firm has submitted DP results of their product against innovator's product Glyxambi Tablets 10mg/5mg in dissolution medias. Analytical method validation/verification	Proposed Pack size	As per SRO
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Firm has summarized information related to nomenclate structure, general properties, solubilities, physical for manufacturing process and validation, batch analysis and justification of specifications, specifications, analytical procedures and validation, batch analysis and justification of specifications of drug substance of both API's separately and diproduct. Module-III Drug Substance: Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubility physical form, manufacturers, description of manufacture process and controls, specifications, analytical procedure and its validation, batch analysis and justification specification, reference standard, container closure syst and stability studies of drug substance of both AI separately. Stability Studies of Drug Substance (Conditions & duration of Stability studies of drug substance of both AI separately. Stability Studies of Drug Substance (Conditions & duration of Stability studies and stability studies from Module-III Drug Product: Firm has submitted data of drug product including description, composition, pharmaceutical developme manufacture, manufacturing process and process cont process validation protocols, control of excipients, controdrug product, specifications, analytical procedure, batch analy justification of specifications, reference standard materials, container closure system and stability. Firm has submitted pharmaceutical equivalence of the product against the Nexum capsule of M/s Getz. Firm has submitted CDP results of their product against innovator's product Glyxambi Tablets 10mg/5mg in dissolution medias.	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan.
nomenclature, structure, general properties, solubility physical form, manufacturers, description of manufacture process and controls, specifications, analytical procedure and its validation, batch analysis and justification specification, reference standard, container closure syst and stability studies of drug substance of both AI separately. Stability Studies of Drug Substance (Conditions & duration of Stability Studies) Both accelerated & long-term stability studies from Portion Pharma has been submitted for Esomeprazole 8.5% pellets as per Zone IVa conditions. Firm has submitted data of drug product including description, composition, pharmaceutical developme manufacture, manufacturing process and process cont process validation protocols, control of excipients, control drug product, specifications, analytical procedure validation of analytical procedures, batch analy justification of specifications, reference standard materials, container closure system and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile Firm has submitted pharmaceutical equivalence of the product against the Nexum capsule of M/s Getz. Firm has submitted CDP results of their product against innovator's product Glyxambi Tablets 10mg/5mg in dissolution medias. Analytical method validation/verification Firm has submitted analytical method validation structure.	Module-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.
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Comparative Dissolution Profile product against the Nexum capsule of M/s Getz. Firm has submitted CDP results of their product against innovator's product Glyxambi Tablets 10mg/5mg in dissolution medias. Analytical method validation/verification Firm has submitted analytical method validation studies.	Module-III Drug Product:	validation of analytical procedures, batch analysis, justification of specifications, reference standard or
	<u>-</u>	Firm has submitted CDP results of their product against the innovator's product Glyxambi Tablets 10mg/5mg in 3
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		STABILITY	Y STUDY DATA		
Manu	facturer of API	M/s Vision Pharmac Kahuta Road, Islamab	euticals (Pvt.) Ltd, Plot No. oad-Pakistan.	22-23, Industrial Triangle,	
API L	ot No.	EMZ046605			
	iption of Pack ainer closure system)	Alu-alu Blister			
Stabil	ity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2$			
Time	Period	Real time: 6 months Accelerated: 6 months	s		
Frequ	ency	Accelerated: 0, 3, 6 (M) Real Time: 0, 3, 6 (M)			
Batch	No.	T-185	T-190	T-191	
Batch	Size	1500 capsules	1500 capsules	1500 capsules	
Manu	facturing Date	03-2023	03-2023	03-2023	
No. of	f Batches		03		
	DOCUMENTS / DA	TA TO BE PROVIDE	D ALONG WITH STABILIT	Y STUDY DATA	
1.	Reference of prev applications with stabil firm (if any)	1 1	N/A		
2.		sued by concerned	Copy of GMP certificate issue inspection conducted on 14-06-		
3.	Documents for the procapproval from DRAP (i	n case of import).	Firm has submitted copy of co 02-2023 specifying 20Kgs of EC pellets 8.5% from M/s Visio	Esomeprazole Magnesium	
4.	Data of stability batches attested respective chromatograms, Raw summary data sheets etc	documents like data sheets, COA,	Firm has submitted analytical re	ecord for product testing.	
5.	Compliance Record 21CFR & audit trail repo		Submitted		
6.	Record of Digital data I and humidity moni chambers (real time and	toring of stability	Not submitted		
Rema	rks of Evaluator:				

Section #	Observations	Firm's response
3.2.S.4.1	Justify the limits of \pm 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 accelerate submitted.	ed) shall be
	Complete batch manufacturing record batches shall be submitted.	pf stability
Decisio	on: Registration Board deferred the case for submi	ssion 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: Empagliflozin25mg Metformin HCl1000mg
	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,

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 Controls, specifications, analytical procedure and justification of specification, reference standard, container closure system and stability studies of drug product. Pharmaceutical Equivalence has been established against the Diampa-M 12.55/500 of M/s Getz		1			
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) Vicinity of products Vicinity Studies of Drug Substance (Conditions & duration of Stability studies) Vicinity Studies of Drug Substance (Conditions & duration of Stability studies) Vicinity Studies of Drug Substance (Conditions & duration of Stability Studies of Drug Substance (Conditions & Drug Substance & Vicinity Studies & Vicinity S				_	•
Conditions & duration of Stability studies TV conditions The firm has submitted detail of manufacturers, description of manufacturing process and controls, specification, specification, specification, specification, reference standard, container closure system and stability studies of drug product. Pharmaceutical Equivalence and Comparative Dissolution Profile 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 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.		Module-III Drug Substance:		structure, general physical form, man manufacturing proces impurity, specificati and its validation, base of specification, ref closure system and	properties, solubility's, nufacturers, description of ess and controls, tests for ons, analytical procedures tch analysis and justification ference standard, container
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 and Comparative Dissolution Profile Analytical method validation/verification of product Method validation studies have submitted 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. Empagifilozin 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) Stability Storage Condition Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Time Period Real time: 6 months Accelerated: 6 months Frequency Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months) Real Time: 0,3,6 (Months) Batch No. EGMF- 12.5/500/T001 EGMF-12.5/500/T002 Batch Size 1000 tablets 1000 tablets 1000 tablets Manufacturing Date 10/2021 11/2021 11/2021 No. of Batches					lrug substances as per Zone
Dissolution Profile 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		Module-III Drug Product:		description of ma controls, specificatio its validation stud- justification of speci- container closure sys	anufacturing process and ns, analytical procedure and lies, batch analysis and fication, reference standard,
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) Stability Storage Condition Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Time Period Real time: 6 months Accelerated: 6 months Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months) Real Time: 0,3,6 (Months) Batch No. EGMF- 12.5/500/T001 Batch Size 1000 tablets 1000 tablets 1000 tablets 11/2021 11/2021 No. of Batches			e and Comparative	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.	
Manufacturer of APIMetformin 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 Provinceal Chemical and medical Rw Materials Base Linhai Zone, Taizhou City, Zhejiang province, China.API Lot No.Metformin Hydrochloride: MEF/11020485Description of Pack (Container closure system)Alu Alu Blisters with aluminum foilStability Storage ConditionReal time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RHTime PeriodReal time: 6 months Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)FrequencyAccelerated: 0,3,6 (Months)Batch No.EGMF- 12.5/500/T001EGMF- 12.5/500/T002Batch Size1000 tablets1000 tablets1000 tabletsManufacturing Date10/202111/202111/2021No. of Batches3		Analytical method validation/	verification of product	including linearity, ra	
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) Stability Storage Condition Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%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 Batch Size 1000 tablets 1000 tablets 1000 tablets 11/2021 No. of Batches			STABILITY STUD	Y DATA	
Description of Pack (Container closure system)	Manufac	cturer of API	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 5 Avenue, Zhejiang Provinceal Chemical and medical Rw Materials Bas		
(Container closure system)Stability Storage ConditionReal time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Time PeriodReal time: 6 months Accelerated: 6 monthsFrequencyAccelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)Batch No.EGMF- 12.5/500/T001EGMF- 	API Lot	No.	Metformin Hydrochlo	oride: MEF/11020485	
Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ Time Period Real time: 6 months Accelerated: 6 months Frequency Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months) Batch No. EGMF- 12.5/500/T001 Batch Size 1000 tablets 1000 tablets 1000 tablets 1000 tablets No. of Batches Accelerated: 100°C ± 2°C / 75% ± 5%RH Real time: 6 months EGMF- 12.5/500/T001 EGMF- 12.5/500/T002 12.5/500/T002 12.5/500/T002 12.5/500/T002 12.5/500/T002 12.5/500/T002 12.5/500/T002			Alu Alu Blisters with	aluminum foil	
Accelerated: 6 months	Stability	Storage Condition			
Real Time: 0,3,6 (Months) Batch No. EGMF- 12.5/500/T001 EGMF- 12.5/500/T002 EGMF- 12.5/500/T002 Batch Size 1000 tablets 1000 tablets 1000 tablets Manufacturing Date 10/2021 11/2021 11/2021 No. of Batches 3	Time Pe	riod		as	
12.5/500/T001 12.5/500/T002 EGMF-12.5/500/1003 Batch Size	Frequen	cy		*	
Manufacturing Date 10/2021 11/2021 11/2021 No. of Batches 3	Batch N	0.	_		EGMF-12.5/500/T003
No. of Batches 3	Batch Si	ze	1000 tablets	1000 tablets	1000 tablets
	Manufac	cturing Date	10/2021	11/2021	11/2021
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	No. of B	atches	3		
		DOCUMENTS / DATA TO B	BE PROVIDED ALO	NG WITH STABILI	ΓΥ STUDY DATA

1.			erence of previous approval of applications a stability study data of the firm (if any)	N/A			
2.		API	proval of API/ DML/GMP certificate of manufacturer issued by concerned alatory authority of country of origin.				
3.			cuments for the procurement of API with roval from DRAP (in case of import).				
4.		atte chro	a of stability batches will be supported by sted respective documents like omatograms, Raw data sheets, COA, mary data sheets etc.	Submitted	l.		
5. Compliance Record of HPLC software 21CFR N/A. & audit trail reports on product testing		N/A.					
6.		and	ord of Digital data logger for temperature humidity monitoring of stability chambers al time and accelerated)	Submitted	l.		
Remark	s of E	valu					
	Sectio #	n	Observations		Firm's response		
	1.1		Justify the validity of submitted application provided fee challan has not been paid as from online <u>eDRAP - Portal</u>				
Decision	ı: Regi	istra	ntion Board deferred the case for submiss	ion of repl	ly to the above cited shortcomin	ngs	
49.	Name	e, ac	ddress of Applicant / Marketing	M/s Wel	wink Pharmaceuticals. Factor dustrial Estate, Gujranwala Ca	y G.T.	
	Name	Name, address of Manufacturing site.		M/s Welwink Pharmaceuticals Factory G.T. Road, Industrial Estate, Gujranwala Cantt.			
	Status	s of	the applicant	☑ Manuf☐ Import☐ Is invgiver)		ontract	
	GMP	GMP status of the firm					
			of approval of manufacturing facility				
			application	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)			
		Dy. No. and date of submission & Details of fee submitted			5818 dated 13-09-2022 Rs.3 12-2021	0,000/-	
	The p	rop	osed proprietary name / brand name	Empame	t 10/1000 mg XR Tablet		
			concentration of drug of Active eutical ingredient (API) per unit	Empaglif	ended Releae Tablet Contains: lozin10mg n HCl1000mg		
	Pharr	naco	otherapeutic Group of (API)	Antidiabe	etic combination		
	Pharr	nace	eutical form of applied drug	Film coat	ed tablet.		
	Refer	ence	e to Finished product specifications	Innovator's specifications.			
			Pack size	As per SRO			
			unit price	As per SF			
			s in reference regulatory authorities	Trijardy		gelheim d.	

	For generic drugs (me-too statu	us)	Diampa-M 5/500 of M/s Getz pharma
	Name and address of API man	ufacturer.	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 Su	mmary)	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 Subst (Conditions & duration of Stab		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 Dissolution Profile	and Comparative	
	Analytical method validation/v	verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
		STABILITY STUD	Y DATA
Manufac	turer of API	Sarigam Valsad, Guja Empagliflozin M/s Zhejiang Tianyu Avenue, Zhejiang Pro	mited, Plot no. 211-213, Road no. 2, G.I.D.C.,
API Lot	No.		

	otion of P		vstem)	Alu Alu Blisters with	aluminum	foil		
-	y Storage			Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH				
Time P	eriod			Real time: 6 months Accelerated: 6 months				
Freque	ncy			Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)				
Batch N	No.			T01	T02		T03	
Batch S	Size			86 packs	86 packs		86 packs	
Manufacturing Date		05-2020	05-2020		05-2020			
No. of 1	Batches			3				
	DOCU	MEN	NTS / DATA TO B	E PROVIDED ALO	NG WITH	STABILIT	Y STUDY DATA	
1.	W	vith s	stability study data		N/A			
2.	A	ΑPI		L/GMP certificate of ued by concerned ountry of origin.	-1			
3.			ments for the proc val from DRAP (in	urement of API with case of import).				
4.	a c	tteste hron	ed respective	will be supported by documents like data sheets, COA,	Submitted			
5.	C	Comp	-	PLC software 21CFR	N/A.			
6.	a	nd h		ogger for temperature of stability chambers d)	Submitted			
Remar	ks of Eva			,				
	Section		Observations			Firm's resp	oonse	
	1.3		manufacturer. • Submit copy of	of valid DML of drug of latest GMP inspecti thin last three years facturers.	on report			
	1.6.5		substance manuf regulatory authori	ML/GMP certificate acturers, issued by ty of country of origin	relevant			
	3.2.S.1.	.3		claration of solub "Practically insoluble the innovator drug	in water"			
	3.2.S.4.	1	procedure sh product manu • Drug substand procedure sh product manu	ce specifications and all be submitted from facturer for Empaglifle ce specifications and all be submitted from facturer and drug for Metformin HCl.	om drug ozin. analytical om drug			

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. 	

Decisio	on: 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: Empagliflozin12.5mg Metformin HCl500mg
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 5 th 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.

Reference of previous apwith stability study data Approval of API/ DM	proval of applications of the firm (if any) L/GMP certificate of sued by concerned country of origin. curement of API with a case of import). s will be supported by documents like data sheets, COA, HPLC software 21CFR product testing logger for temperature g of stability chambers	N/A Submitted. N/A.	TY STUDY DATA
Reference of previous ap with stability study data Approval of API/ DM API manufacturer is regulatory authority of c Documents for the procapproval from DRAP (in Data of stability batches attested respective chromatograms, Raw summary data sheets etc Compliance Record of H& audit trail reports on p Record of Digital data I and humidity monitoring	proval of applications of the firm (if any) L/GMP certificate of sued by concerned country of origin. curement of API with a case of import). s will be supported by documents like data sheets, COA, HPLC software 21CFR product testing logger for temperature g of stability chambers	N/A Submitted. N/A.	TY STUDY DATA
Reference of previous are with stability study data Approval of API/ DM API manufacturer is regulatory authority of compound proval from DRAP (in Data of stability batches attested respective chromatograms, Raw summary data sheets etc. Compliance Record of Factories and Compound provided in the compound proval from DRAP (in Data of stability batches attested respective chromatograms, Raw summary data sheets etc. Compliance Record of Factories and the compound provided provide	pproval of applications of the firm (if any) L/GMP certificate of sued by concerned country of origin. curement of API with a case of import). s will be supported by documents like data sheets, COA, and the conduct testing	N/A Submitted. N/A.	TY STUDY DATA
Reference of previous are with stability study data Approval of API/ DM API manufacturer is regulatory authority of compound proval from DRAP (in Data of stability batches attested respective chromatograms, Raw summary data sheets etc.)	pproval of applications of the firm (if any) L/GMP certificate of sued by concerned country of origin. curement of API with a case of import). s will be supported by documents like data sheets, COA,	N/A Submitted.	TY STUDY DATA
Reference of previous apwith stability study data Approval of API/ DM API manufacturer is regulatory authority of c	pproval of applications of the firm (if any) L/GMP certificate of sued by concerned country of origin. curement of API with	N/A 	TY STUDY DATA
Reference of previous apwith stability study data Approval of API/ DM API manufacturer is	BE PROVIDED ALO opproval of applications of the firm (if any) L/GMP certificate of sued by concerned	N/A	TY STUDY DATA
DOCUMENTS / DATA TO H Reference of previous ap	BE PROVIDED ALO	T	TY STUDY DATA
		NG WITH STABILI	I'Y STUDY DATA
		11/2021	11/2021
			11/2021
	12.5/500/T001	12.5/500/T002	EGMF-12.5/500/T003
су	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
riod	Real time: 6 months Accelerated: 6 month	ns	
Storage Condition			
ion of Pack er closure system)	Alu Alu Blisters with	aluminum foil	
No.	Metformin Hydrochl	oride: MEF/11020485	
turer of API	M/s Aarti Drugs Li Sarigam Valsad, Guj Empagliflozin M/s Zhejiang Tiany Avenue, Zhejiang Pro	mited, Plot no. 211-2 arat India. u Pharmaceutical Co., ovinceal Chemical and	Ltd., No. 15, Donghai 5 th medical Rw Materials Base
0.470	1		
Analytical method validation/		including linearity, raspecificity.	idies have submitted inge, accuracy, precision,
Dissolution Profile		against the Diampa- pharma along with Cl are in the acceptable	
	Analytical method validation/ Analytical method validation/ turer of API No. ion of Pack er closure system) Storage Condition riod cy cy co. ze turing Date	Analytical method validation/verification of product STABILITY STUD turer of API Metformin Hydroch M/s Aarti Drugs Li Sarigam Valsad, Guj. Empagliflozin M/s Zhejiang Tiany Avenue, Zhejiang Pre Linhai Zone, Taizhou No. Metformin Hydrochle ion of Pack er closure system) Storage Condition Real time: 30°C ± 2° Accelerated: 40°C ± riod Real time: 6 months Accelerated: 6 month Accelerated: 0,3,6 (Month) EGMF- 12.5/500/T001 Zee 1000 tablets	Analytical method validation/verification of product Analytical method validation/verification of product Analytical method validation/verification of product STABILITY STUDY DATA turer of API Metformin Hydrochloride M/s Aarti Drugs Limited, Plot no. 211-2 Sarigam Valsad, Gujarat India. Empagliflozin M/s Zhejiang Tianyu Pharmaceutical Co., Avenue, Zhejiang Provinceal Chemical and Linhai Zone, Taizhou City, Zhejiang provin No. Metformin Hydrochloride: MEF/11020485 ton of Pack er closure system) Storage Condition Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH accelerated: 6 months Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months) Real Time: 0,3,6 (Months) BedMF- 12.5/500/T001 EGMF- 12.5/500/T002 Tec 1000 tablets 1000 tablets 1000 tablets 11/2021

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.

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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 Ingelheir Pharmaceuticals, Inc. is USFDA Approved.	
For generic drugs (me-too status)	Diampa-M 5/500 of M/s Getz pharma	
	Metformin Hydrochloride M/s Smruthi Organics ltd. Plot no. A-27, M.I.D. Chincholi, Taluka Mohol Solapur Maharashtra India Empagliflozin M/s Fuxin Long Rui Pharmaceutical Co, Ltd China Address: Fluoride Industrial Park, Fumen County (Yi Ma Tu), Fuxin City, Liaonin Province -123000, China1	
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PE 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 procedure and its validation, batch analysis and justification of specification, reference standard, contained 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 Zor IV conditions	

	Module-III Drug Product:		description of ma controls, specification its validation stud justification of specif	red detail of manufacturers, nufacturing process and ns, analytical procedure and ies, batch analysis and fication, reference standard, tem and stability studies of
	Pharmaceutical Equivalence Dissolution Profile	and Comparative	against the Xenglu-	valence has been established Met tablet of M/s Hilton OP studies wherein values f2 range.
	Analytical method validation/v	verification of product		studies have submitted range, accuracy, precision,
		STABILITY STUD	Y 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		
	ion of Pack er closure system)	Alu Alu Blisters with aluminum foil		
Stability	Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequen	су	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch N	0.	T037	T038	T039
Batch Si	ze	1200 tab	1200 tab	1200 tab
Manufac	cturing Date	21-09-2021	22-09-2021	23-09-2021
No. of B	atches	3		
52.	Name, address of Applicant Authorization Holder	/ Marketing	M/s Welmark Pharr Plot #122 Phase 5, B	naceuticals. lock B, Industrial Hattar
	Name, address of Manufacturi	ng 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 certific	ate 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)	
	Minutes of 335 th meeting of	Registration Board		49

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 Ingelheir 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. Chincholi, Taluka Mohol Solapur Maharashtr India Empagliflozin M/s Fuxin Long Rui Pharmaceutical Co, Ltd China Address: Fluoride Industrial Park, Fumer County (Yi Ma Tu), Fuxin City, Liaonir Province -123000, China1
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-P template. Summarized information related nomenclature, structure, general properties, Solubilities, physical form, manufacturer description of manufacturing process ar controls, impurities, specifications, analytic procedures and its verification, batch analysis ar justification of specification, reference standar container closure system and stability studies drug substance and drug product is submitted.
Module-III Drug Substance:	The firm as submitted detail of nomenclatur structure, general properties, solubility' physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedure and its validation, batch analysis and justification of specification, reference standard, contained closure system and stability studies of drusubstance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted for both drug substances as per Zoi IV conditions
Module-III Drug Product:	The firm has submitted detail of manufacturer description of manufacturing process are controls, specifications, analytical procedure are its validation studies, batch analysis are justification of specification, reference standare

			container closure sys	tem and stability studies of
	Pharmaceutical Equivalence and Comparation 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/v	verification of product Method validation studies have sub- including linearity, range, accuracy, pre- specificity.		
	,	STABILITY STUD	Y DATA	
Manufacturer of API		Metformin Hydrochloride M/s Smruthi Organics Itd. 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 Hydrochlo Empagliflozin: E-201		
	ion of Pack er closure system)	Alu Alu Blisters with	aluminum foil	
Stability	Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Pe	riod	Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch N	0.	T040	T041	T042
Batch Si	ze	1200 tab	1200 tab	1200 tab
Manufac	cturing Date	12-10-2021	13-10-2021	14-10-2021
No. of B	atches	3		
53.	Name, address of Applicant Authorization Holder	/ Marketing	M/s Welmark Phari Plot #122 Phase 5, B	naceuticals. Flock B, Industrial Hattar
	Name, address of Manufacturi	ng 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 feasubmitted		Dy.No 22078 dated 03-08-2022 Rs.30,000/-dated 30-06-2022	
	The proposed proprietary nam	e / brand name	Empazin M 5/500 mg Tablet	

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	
• •	Trijardy by Boehringer Ingelhein Pharmaceuticals, Inc. is USFDA Approved.	
For generic drugs (me-too status)	Diampa-M 5/500 of M/s Getz pharma	
	Metformin Hydrochloride M/s Smruthi Organics ltd. Plot no. A-27, M.I.D. Chincholi, Taluka Mohol Solapur Maharashtr India Empagliflozin M/s Fuxin Long Rui Pharmaceutical Co, Ltd China Address: Fluoride Industrial Park, Fumer County (Yi Ma Tu), Fuxin City, Liaonin Province -123000, China1	
	Firm has submitted QOS as per WHO QOS-P template. Summarized information related nomenclature, structure, general properties, Solubilities, physical form, manufacturer description of manufacturing process are controls, impurities, specifications, analytic procedures and its verification, batch analysis are justification of specification, reference standard container closure system and stability studies of drug substance and drug product is submitted.	
	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, contained closure system and stability studies of drug substance.	
	Submitted for both drug substances as per Zor IV conditions	
	The firm has submitted detail of manufacturer description of manufacturing process ar controls, specifications, analytical procedure ar its validation studies, batch analysis ar justification of specification, reference standar container closure system and stability studies drug product.	
Pharmaceutical Equivalence and Comparative	Pharmaceutical Equivalence has been established against the Xenglu-Met tablet of M/s Hilto	

			pharma along with CI are in the acceptable	OP studies wherein values f2 range.	
			Method validation studies have submitted including linearity, range, accuracy, precision, specificity.		
		STABILITY STUD	Y 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 Hydrochlo Empagliflozin: E-201			
	ion of Pack er 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 Pe	riod	Real time: 6 months Accelerated: 6 months			
Frequen	су	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)			
Batch N	0.	T034	T035	T036	
Batch Si	ze	1200 tab	1200 tab	1200 tab	
Manufac	cturing Date	13-09-2021	14-09-2021	15-09-2021	
No. of B	atches	3			
	DOCUMENTS / DATA TO	BE PROVIDED ALO	NG WITH STABILIT	TY STUDY DATA	
1.	Reference of previous a with stability study data	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).		commercial invoice Peshawar, DRAP date Empagliflozin. Metformin: Firm commercial invoice	attested by AD I&E ed 18-01-2019 for 410gm of	
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	Submitted.
	and humidity monitoring of stability chambers	
	(real time and accelerated)	

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

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.

submitted in the registration application.			
M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan			
M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan			
 ☑ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver) 			
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			
Firm has submitted copy of letter of grant of section dated 15-12-2014 specifying Tablet (General) section.			
☑ New Drug Product (NDP)☐ Generic Drug Product (GDP)			
☑ Domestic sale☐ Export sale☐ Domestic and Export sales			
Dy.No 12632 dated 24-05-2022			
Rs.75,000/- dated 12-05-2022			
Empala 25/5 mg Tablet			
Each Film coated Tablet contains: Empagliflozin			
Empagliflozin: Anti-Diabetic Linagliptin: Anti-Diabetic			
Pink color hexagonal shape film coated tablets			
Innovator's Specifications			
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 06 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 06 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ 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 dissolution medias.	Tablets 10mg/5mg in 3	
	Analytical method validation/verification of product		Firm has submitted analytical reports for drug substance as wel		
		STABILIT	TY STUDY DATA		
Address: No.1, Yur Linagliptin: Name: Glenmark L Address: Plot No 3		urmaceutical (Group) Company Limited. nan Street, Kaifeng, Henan Province, China. ife Sciences Limited 109, GIDC Industrial Estate, Ankleshwar ujarat - 393 002, India			
API L	ot No.	Empagliflozin: HF: Linagliptin: 801900			
	ption of Pack niner closure system)	Alu-alu Blister			
Stabili	ty Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm$	C / 65% ± 5%RH 2°C / 75% ± 5%RH		
Time I	Period	Real time: 6 months Accelerated: 6 mont			
Freque	ency	Accelerated: 0, 3, 6 Real Time: 0, 3, 6 (1)			
Batch	No.	T-01	T-02	T-03	
Batch	Size	1500 Tablets	1500 Tablets	1500 Tablets	
Manuf	Facturing Date	01-2020	01-2020	01-2020	
No. of	Batches		03		
	DOCUMENTS / DA	TA TO BE PROVID	ED ALONG WITH STABILIT	TY STUDY DATA	
1.			in 320 th meeting of Registration following points: iii. The HPLC software is	10mg which was approved Board. The report confirms	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			9 issued by China Food and of GMP Certificate (No. issued by Food and Drugs State India. The certificate	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Empagliflozin: Firm has submitted copy of cor 31-01-2019 specifying 5Kgs of is cleared by AD (I&E) DRAP, Linagliptin:	Empagliflozin. The invoice	

		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.	
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)	

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.

	ame, address of Applicant / Iarketing Authorization Holder	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Plot no. 209, Sector 23, Korangi Industrial area, Karachi
	ame, address of Manufacturing te.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Plot no. 209, Sector 23, Korangi Industrial area, Karachi
St	tatus of the applicant	☑ Manufacturer☐ Importer☐ Is involved in none of the above (contract giver)
G	MP status of the firm	Firm has submitted copy of GMP certificate based on inspection conducted on 26-06-2019.
	vidence of approval of nanufacturing facility	Firm has submitted copy of letter of Renewal of DML issued by Secretary CLB dated 21-06-2021 specifying Sterile Infusion (General) section.
St	tatus of application	☑ New Drug Product (NDP)☐ Generic Drug Product (GDP)
	ntended use of pharmaceutical roduct	☑ Domestic sale☐ Export sale☐ Domestic and Export sales
	y. No. and date of submission & etails of fee submitted	Dy.No 5851 dated 03-03-2022 Rs.30,000/- dated 10-11-2021
	he proposed proprietary name / rand name	Boschstat 12.5mg/50ml Injection
A	trength / concentration of drug of active Pharmaceutical ingredient API) per unit	Each ml Contains: Tirofiban HCl Eq. to Tirofiban0.25mg
	harmacotherapeutic Group of API)	Anti thrombic agent
	harmaceutical form of applied	Injection
D.	eference 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 (n	ne-too status)	Aggrastat injection of M/s Atco Laboratories (Reg.#025299)
		M/s Xi'an Wanlong Pharmaceutical Co., Ltd. no. 5 Chuangxin road, New Industrial park, gaoxin District, Xi'an Shaanxi, China
Module-II (Qual Summary)	lity Overall	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 Su	bstance:	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 Substance (Conditions & durat Stability studies)		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 6 months.
Module-III Drug Pro	oduct:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Eq Comparative Dissol		Firm has submitted pharmaceutical equivalence of their product against the innovator's product Aggrastat injection of M/s Siegfried
Analytical method validation/verification	on of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
	ST	ABILITY STUDY DATA
Manufacturer of API		anlong Pharmaceutical Co., Ltd. no. 5 Chuangxin road, New , gaoxin District, Xi'an Shaanxi, China
API Lot No.	YD-20201101	-Н
Description of Pack (Container closure system) Glass vial		
Stability Storage Condition		$C \pm 2^{\circ}C / 65\% \pm 5\%RH$ $0^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%RH$
Time Period Real time: 6 m Accelerated: 6		

Frequ	ency	cy Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)					
Batch No. TR-BOINJ-		-02	TR-BO	DINJ-03	TR-BOINJ-04		
Batch	Size		500 vial	S	500	vials	500 vials
Manu	facturing Date		05-2021	-	05-	2021	05-2021
No. o	f Batches					03	
	DOCUMENT	S/D	ATA TO BE P	ROVID	ED ALON	G WITH ST	SABILITY STUDY DATA
1.	Reference of papplications			Firm has referred to previously approved product of Boschofen 400mg/100ml on basis of PSI, presented in 296 th 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.	certificate of	API oncern	ed regulatory			d copy of G 24 issued by	MP Certificate (No. SN20190380 CFDA.
3.		oval f		specify	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.	supported by documents li	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary		Firm h	as submittec	l analytical re	ecord for product testing.
5.	software 21C	•		Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.			
6.	temperature	and stab	humidity ility chambers	humidi	ity monitor		gital data logger for temperature an I time and accelerated stabilit
Rema	rks of Evaluato						
	Section #		ervations			Firm's res	
	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. 		inspection	submitted copy of panel report dated 10-04-2023 Good cGMP compliance.		
	3.2.S.4.4	chror wave chror differ subst	matograms of rent form that ance analytication shall be	condit leclared Assay specific ical	tion of on y test is ed in drug procedure.	find attache on same v related s performed we perfor validation of as per subi	as Specified in drug analytical procedure kindly ed assay results performed wave length (227 nm) as ubstance analysis also on same wave length and rmed analytical method on same wave length as well mitted analytical procedure art enclosed for ready

3.2.P.5.1	Justification shall be submitted for limits of filled volume.	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. 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 6 th 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

	Name, address of Man	ufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi		
57.	Name, address of App Authorization Holder		M/s Scilife Pharma (Pvt.) I Amir Khusro Road, Karad	* *	
No. of E	1		03		
Manufacturing Date		03-2021	03-2021	03-2021	
Batch Size 15		1500 tab	1500 tab	1500 tab	
Batch No. 046B21		046B21	047B21	048B21	
		Accelerated: 0, 2, 4, 6 (Meal Time: 0, 3, 6 (Mont			
		Real time: 6 months Accelerated: 6 months			
-	y Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
_	tion of Pack ner closure system)	Alu-Alu blister packed in	n unit carton		
API Lot	t No.	A-35212009047 / H-E-2			
	I .	STABILITY ST	** *		
	Analytical method v	ralidation/verification of			
	Pharmaceutical equivalence and comparative dissolution profile		description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has submitted Compartitive dissolution profile against Xenglu Met XR 5+1000mg Tablet of Hilton Pharma.		
	Module-III (Drug Prod	uct):	hydrochloride conducted a The stability study data is till Firm has submitted data of	t 30±2°C, 75%±5% RH. ll 60 months. drug product including its	
			The real time stability conducted at 30±2°C, 65% study data is till 26 months. The real time stability	6±5% RH. The stability	
	Stability studies		Firm has submitted stability both API at accelerated as w		
			both sources related to general properties, solut manufacturers, description and controls, impurities, procedures and its validar justification of specification container closure system an substance.	pilities, physical form, of manufacturing process specifications, analytical tion, batch analysis and tion, reference standard,	
	1				

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 Sub	etoneo)	Firm has submitted detailed	d drug substance data for
			Firm has submitted detailed both sources related to general properties, solub manufacturers, description and controls, impurities, procedures and its validat justification of specification container closure system an substance.	nomenclature, structure, bilities, physical form, of manufacturing process specifications, analytical tion, batch analysis and ion, reference standard,
	Stability studies		Firm has submitted stability both API at accelerated as w	
			The real time stability conducted at 30±2°C, 65% study data is till 26 months.	%±5% RH. The stability
			The real time stability hydrochloride conducted a The stability study data is till	
	Module-III (Drug Product): Pharmaceutical equivalence and comparative dissolution profile		Firm has submitted data of description, composit development, manufacture and process control, process control of excipients, conspecifications, analytical panalytical procedures, batch specifications, reference container closure system and	ion, pharmaceutical, manufacturing process ess validation protocols, ontrol of drug product, procedures, validation of analysis, justification of standard or materials,
			Firm has submitted Compartitive dissolution profile against Xenglu Met XR 5+1000mg Tablet of Hilton Pharma.	
	Analytical method product	validation/verification of	Firm has submitted analytical method validation studies for the applied product.	
		STABILITY ST	ΓUDY DATA	
API Lot	t No.	A-35212009047 / H-E-2	20201125-D03-E06-02	
	tion of Pack ner closure system)	Alu-Alu blister packed i	n unit carton	
Stability	y Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time Pe	eriod	Real time: 6 months Accelerated: 6 months		
Frequency Accelerated: 0, 2, 4, 6 (MReal Time: 0, 3, 6 (Mont		•		
Batch N	Batch No. 049B21		050B21	051B21
Batch S	Batch Size 1500 tab		1500 tab	1500 tab
Manufa	cturing Date	03-2021	03-2021	03-2021
No. of I	Batches		03	1
		Administrati	ive Portion	
1.			Firm has referred to onsite product Glusimet XR 50/50 XR 50/1000mg Tablets whi	00mg Tablets & Glusimet

		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	Copy of DML certificate No. Liao20150233 issued
	authority of country of origin.	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
Remark	cs 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 inprocess 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	

			☐ Is involved in none of the above (contract giver)			
Application Form Dy. No / of submission	11		Form 5F: SP2-GW7-LLZN dated 09-02-2024			
Details of fee submitted	Details of fee submitted			Rs.30,000/- dated 11-01-2024		
The proposed proprietary na	The proposed proprietary name / brand name			Osotax 2gm injection IV		
Strength / concentration of of Pharmaceutical ingredient (vial contains: iaxone as sodium	2g	
Pharmacotherapeutic Group	of (API)		Cephalosporin Antibiotic			
Reference to Finished produ	ct specification	ons	ns USP			
	EVAL	UATI	ON O	F DATA		
GMP status of the firm			P certi 3-2022		sis of inspection conducted on	
Evidence of approval of manufactu	ring facility	l .	ring g		suance of additional section Injection (Cephalosporin)	
Proposed Pack size		1's				
Proposed unit price		As pe	er SRC)		
The status in reference regulatory a	uthorities	MHR	RA app	proved		
For generic drugs (me-too status)		Oxid	Oxidil 2g IV Injection by SAMI Pharmaceuticals.			
Name and address of API manufac	turer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China.				
Module-II (Quality Overall Summa	ary)	Firm	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				abmitted stability st as per zone IV-A co	udy data of 3 batches of drug anditions.	
Module-III Drug Product:		Firm has submitted data of drug product as per module 3.2.P.				
Pharmaceutical Equivalence and C Dissolution Profile	omparative	Firm has performed pharmaceutical equivalence against the product Oxidil 2g IV Injection by Sami Pharmaceuticals				
Analytical method validation/verifi product	cation of	Firm has submitted analytical method validation study reports for drug substance as well as drug product.				
	STABI	LITY	STUI	DY DATA		
API Lot No.	Q012212069	9				
Description of Pack (Container closure system)	Glass vial					
Stability Storage Condition				C ±2°C / 65%±5% RH 40°C ±2°C / 75%±5% RH		
Time Period	ne Period Real time: 3 month Accelerated: 3 mo					
Frequency	Accelerated Real Time:					
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 T	O BE PROVI	DED ALONG WITH STABILITY STUDY DATA
Reference of previous approval of applications with stability study data of the firm (if any)		N/A
		* •
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.
1		Firm has submitted analytical record for product stability studies.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Submitted
humidity monitoring of stability chambers (real		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 6 th month time point stability data for both	Submitted.
		accelerated and long term stability studies.	

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 290^{th} 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 of submission	& date	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 na	ame	Tazopip Injection 2.25 g		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	e	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 specificati	ons	USP		
	EVAI	UATI	ON OF DATA		
GMP status of the firm			cGMP certificate issued on basis of inspection conducted on 08-08-2022		
Evide	nce of approval of manufacturing facility		grant of DML#000971 including "Dry Powder Injection (Penicillin) section		
Propo	sed Pack size	1's			
Propo	sed unit price	As po	As per SRO		
The s	tatus in reference regulatory authorities	Zosy	Zosyn ® Injection is Approved in USFDA		
For go	eneric drugs (me-too status)	Tanz	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.		
Modu	lle-II (Quality Overall Summary)	Firm	Firm has submitted QOS as per WHO QOS-PD template.		
Modu	le-III Drug Substance:		Firm has submitted detailed drug substance data as per module 3.2.S.		
	ity Studies of Drug Substance litions & duration of Stability studies)		Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.		
Modu	lle-III Drug Product:	Firm	has submitted data of drug product as per module 3.2.P.		
Dissolution Profile		produ	Firm has performed pharmaceutical equivalence against the product Tanzo Injetion 4.5gm Injection by M/s Bosc Pharmaceuticals		
Analy produ	rtical method validation/verification of ct		has submitted analytical method validation study reports rug substance as well as drug product.		
	STABI	LITY	STUDY DATA		
API I	Lot No. HF2164D3				

	ption of Pack hiner closure system)	Glass vial				
	ty Storage Condition	Real time: 30°C ±2°C / 65%±5% RH Accelerated: 40°C ±2°C / 75%±5% RH				
Time l	Period	Real time: 3 months Accelerated: 3 months				
Freque	ency	Accelerated: 0 Real Time: 0,	0, 3,	6 (Mo		
Batch	No.	T1	<u> </u>	`	T2	
Batch	Size	2000 vials			2000 vials	
Manuf	facturing Date	04-2023			04-2023	
No. of	Batches	03				
	DOCUMENTS / DATA T	O BE PROVI	DED	ALO	NG WITH STABILITY	STUDY DATA
1	ence of previous approval of a tability study data of the firm	* *	N/A			
Appromanuf	val of API/ DML/GMP certifacturer issued by concernedity of country of origin.	ificate of API			submitted copy of DML (20160009	Certificate (No.2016009)
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. 			
atteste chrom data sh	atograms, Raw data sheets, C neets etc.	nents like OA, summary	stud	ies.	submitted analytical reco	ord for product stability
	liance Record of HPLC softw rail reports on product testing		N/A			
humid	d of Digital data logger for tentity monitoring of stability chand accelerated)	_	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.			
Evalua	ation by PEC ^{II} :					
 Decision: Approved. Manufacturer will place first three proposed shelf life and on accelerated sthe registration application. Manufacturer will perform process value submitted in the registration application. 			tudie alida	es for	six months as per the co	mmitment submitted in
60.	Name, address of Applican Authorization Holder	ant / Marketing		Indu	Skywin Pharmaceuticals strial Estate, Phase II Sh ore, Pakistan.	*
	Name, address of Manufactu	facturing site.			Skywin Pharmaceuticals trial Estate, Phase II She tan.	
	Status of the applicant			□Im	anufacturer porter involved in none of the ab	ove (contract giver)

I I	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		
Т	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		
P	Pharmacotherapeutic Group	of (API)		β-Lactamase inhibitor		
R	Reference to Finished produc	ct specification	ons	USP		
		EVAL	UATI	ON O	F DATA	
GMP sta	atus of the firm			P certi 3-2022		is of inspection conducted on
Evidenc	e of approval of manufactur	ring facility	_		AL#000971 including section	g "Dry Powder Injection
Propose	d Pack size		1's			
Propose	d unit price		As pe	er SRC)	
The state	us in reference regulatory au	ıthorities	Zosy	n ® In	jection is Approved	in USFDA
For gene	eric drugs (me-too status)		Tanz	o Injec	ction 4.5gm by Bosc	h Pharmaceuticals.
Name ar	nd address of API manufactor	urer.		M/s Shandong Anxin Pharmaceutical Co., Ltd, No.849 Dongjia Town, Licheng District, Jinan, Shandong, 250105 China.		
Module-	-II (Quality Overall Summar	ry)	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.			
	Studies of Drug Substance tions & duration of Stability		1		s per zone IV-A cor	dy data of 3 batches of drug aditions.
Module-	-III Drug Product:		Firm	has su	bmitted data of drug	g product as per module 3.2.P.
	ceutical Equivalence and Co tion Profile	omparative	Firm has performed pharmaceutical equivalence against the product Tanzo Injetion 4.5gm Injection by M/s Bosch Pharmaceuticals			
Analytic product	cal method validation/verific	cation of	Firm has submitted analytical method validation study reports for drug substance as well as drug product.			
		STABI	LITY	STUL	OY DATA	
API Lot	No.	HF2164D3				
	tion of Pack ner closure system)	Glass vial				
Stability	Storage Condition			£±2°C / 65%±5% RH °C ±2°C / 75%±5% RH		
Time Pe	eriod	Real time: 3 Accelerated:				
Frequen	cy	Accelerated: 0, 3, Real Time: 0, 3, 6				
Batch N	0.	T1			T2	
Batch Si	ize	2000 vials			2000 vials	
Manufac	cturing Date	04-2023			04-2023	
No. of B	Batches	03				

DOCUMENTS / DATA TO BE PROVI	IDED 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.
	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) Figuration by PEC ^{II} :	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 Paroxetine10mg
	Pharmacotherapeutic Group of (API)	Selective Serotonin Reuptake Inhibitor / Anti- Depressants

		-		
Reference to Finished pro	-		per Innovator specification	ns
	EVALU		OF DATA	100 1 111 02 2021
GMP status of the firm			• • • • • • • • • • • • • • • • • • • •	ertificate dated 11-03-2024.
Evidence of approval of manufac	cturing facility		submitted copy of letter of specifying Syrup section.	f grant of section dated 25-
Proposed Pack size		1's		
Proposed unit price		As per S	RO	
The status in reference regulator	y authorities	Paxil 10	mg base/5mL Oral Suspens	ion (USFDA Approved)
For generic drugs (me-too status)	NA		
Name and address of API manuf	acturer.	•	jiang Huahai Pharmaceutic Xunqiao, Linhai, Zhejiang	
Module-II (Quality Overall Sum	mary)	Firm has	submitted QOS as per WH	IO QOS-PD template.
Module-III Drug Substance:		Firm has	submitted detailed drug su 3.2.S.	bstance data as per
Stability Studies of Drug Substat (Conditions & duration of Stabil			submitted stability study de as per zone IV-A condition	9
Module-III Drug Product:		Firm has	submitted data of drug pro	oduct as per module 3.2.P.
Dissolution Profile		Firm has submitted pharmaceutical equivalence of their product against the Paxil 10mg/5mL Oral Suspension manufactured by GSK.		
Analytical method validation/ver product	rification of	Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
	STABII	LITY ST	UDY DATA	
API Lot No.	5669-21-032	•		
Description of Pack (Container closure system)	Plastic bottle			
Stability Storage Condition		$0^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%RH$ $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%RH$		
Time Period	Real time: 6 Accelerated:		S	
Frequency	Accelerated: Real Time: 0			
Batch No.	GN-0	001	GN-002	
Batch Size	200	00	2000	
Manufacturing Date	04-20	022	04-2022	
No. of Batches	02			
DOCUMENTS / DATA	A TO BE PROV	IDED A	LONG WITH STABILIT	Y 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).		cleared	on 06-11-2021 specifying	ercial invoice HH20212406 53kg of Paroxetine HCL ared by AD (I&E) DRAP,

	Firm has submitted analytical record for product stability studies.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Firm has submitted record of 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.
- ➤ 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 Name, address of Manufacturing site.		M/s Stallion Pharmaceuticals, PVT, LTD. Plot No. 581, Sundar Industrial Estate, Raiwind Road, Lahore	
			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 & of submission	date	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 na	me	Stamentin 625mg Tablet	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each Tablet Contains: Amoxicillin as Trihydrate500mg Clavulanic acid as Potassium Clavulanate 125 mg	
	Pharmacotherapeutic Group of (API)		Antibacterial for systematic use, carbapenem.	
	Reference to Finished product specification	ns	USP	
	EVAL	UATI	ON OF DATA	
GMP	status of the firm		P certificate issued on basis of inspection conducted on 9-2022	
		Firm has submitted letter of issuance of additional section declaring grant of Penicillin (Tablet) section.		
Propo	Proposed Pack size 6's			
Propo	Proposed unit price As p		er SRO	
The st	ratus in reference regulatory authorities	Appr	oved by US FDA	
For ge	eneric drugs (me-too status)	Calar	alamox 625 mg Table of M/s Bosch Pharma (Reg.#021510)	

7 F N		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 Summa	ry)	Firm has su	bmitted QOS as per WHC	QOS-PD template.	
Module-III Drug Substance:		Firm has su module 3.2	ibmitted detailed drug subs	stance data as per	
Stability Studies of Drug Substance (Conditions & duration of Stability			ibmitted stability study dat s per zone IV-A condition		
Module-III Drug Product:		Firm has su	bmitted data of drug produ	act as per module 3.2.P.	
Pharmaceutical Equivalence and Co Dissolution Profile	omparative	product ag Tablet. Firm has s	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/verific product	cation of		bmitted analytical method bstance as well as drug pro	7 1	
	STABII	LITY STUI	DY DATA		
API Lot No.	Potassium Cl Amoxicillin		3572301434 33PN3-20023		
Description of Pack (Container closure system)	Aluminium f	pil			
Stability Storage Condition		0°C ±2°C / 65%±5% RH 40°C ±2°C / 75%±5% RH			
Time Period	Real time: 6 Accelerated:				
Frequency		(a), 3, 6 (Months) (b), 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 T	O BE PROV	IDED ALC	NG WITH STABILITY	STUDY DATA	
Reference of previous approval of a with stability study data of the firm		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 attested respective docum chromatograms, Raw data sheets, C data sheets etc.	nents like		ubmitted analytical record	for product testing.	

				1		
_	Compliance Record of HPLC software 21CFR & Subn audit trail reports on product testing				mitted	
Recor humid	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real humidity monitoring of stability chambers)				n has submitted record of data logger for temperature and idity monitoring of real time and accelerated stability mbers.	
Evalu	ation by	PEC":		1		
	Sr.#	Section#	Observation		Firm's response	
	1.	3.2.P.8.3	Submit stability stud	ies da	ta of 6 th month time point. Submitted	
Decisi	propo the re Manu	facturer wil sed shelf life gistration ap facturer wi	e and on accelerated oplication.	studio valida	ion batches on long term stability studies throughout es for six months as per the commitment submitted in ation of first three batches as per the commitment	
63.		address of A	Applicant / Marketing der	3	M/s Stallion Pharmaceuticals, PVT, LTD. Plot No. 581, Sundar Industrial Estate, Raiwind Road, Lahore	
	Name,	address of M	anufacturing site.		M/s Stallion Pharmaceuticals, PVT, LTD. Plot No. 581, Sundar Industrial Estate, Raiwind Road, Lahore	
	Status	of the applica	int		 ✓ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver) 	
	Application of subm		y. No / Tracking ID &	date	Form 5F: RDB-6H8-83E4 dated 22-03-2024	
	Details	of fee submi	tted		Rs.30,000/- dated 08-09-2023	
	The pro	oposed propr	ietary name / brand na	me	Stamentin 375mg Tablet	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit			Each Tablet Contains: Amoxicillin as Trihydrate250mg Clavulanic acid as Potassium Clavulanate 125 mg		
	Pharma	acotherapeuti	c Group of (API)		Antibacterial for systematic use, carbapenem.	
	Referen	nce to Finish	ed product specificatio	ns	USP	
			EVAL	UATI	ON OF DATA	
GMP	status of	the firm			P certificate issued on basis of inspection conducted on 9-2022	
Evide	nce of ap	oproval of ma	nnufacturing facility		m has submitted letter of issuance of additional section claring grant of Penicillin (Tablet) section.	
Propo	sed Pack	size		6's	S	
•	sed unit	•		_	per SRO	
The status in reference regulatory authorities Appr		proved by US FDA				
			alamox 625 mg Table of M/s Bosch Pharma (Reg.#021510)			
7/1, 2 Pota No. 3		7/1, N Pota No. 2	xicillin trihydrate: M/s. Saakh Pharma Pvt. Ltd. Plot # C-North West Industrial Zone, Port Qasim, Karachi, Pakistan ssium Clavulanate: M/s Zhuhai United Labs (CHINA) 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, agdong Province, 519040 P.R. China			
Modu	le-II (Qu	ality Overall	Summary)	Firm	has submitted QOS as per WHO QOS-PD template.	
Modu	le-III Dr	ug Substance	: :		has submitted detailed drug substance data as per ale 3.2.S.	

		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.			
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/verific product			abmitted analytical method ostance as well as drug pr	d validation study reports roduct.	
	STABIL	ITY STUI	OY DATA		
API Lot No.	Potassium Cl Amoxicillin				
Description of Pack (Container closure system)	Aluminium f	oil			
Stability Storage Condition	Real time: 30 Accelerated:		5%±5% RH / 75%±5% RH		
Time Period	Real time: 6 : Accelerated:				
Frequency	Accelerated: Real Time: 0				
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 T	O BE PROV	IDED ALC	NG WITH STABILITY	Y STUDY DATA	
Reference of previous approval of a with stability study data of the firm		N/A			
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Director Identification of the conducted Potassium	&E, DRAP Karachi issu on 7-10-2022.	ficate issued by Additional and on basis of inspection submitted GMP certificate valid till 05-12-2023.	
Documents for the procurement of A approval from DRAP (in case of im		pharm Firm 1	na. nas submitted Clearance	al invoice from M/s Saakh certificate issued dated 03- f 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 s	ubmitted analytical recor	d 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)				ogger for temperature and and accelerated stability	
Evaluation by PEC ^{II} :					
Sr.# Section# Observ	ation		I	Firm's response	

	1. 3.2.P.8.3 Submit stability studies data of 6 th month time point. Submitted					
Decisi	propo the re Manu	facturer wil sed shelf life gistration a facturer wi	e and on accelerated pplication.	studio valida	tion batches on long term stability studies throughout es for six months as per the commitment submitted in ation of first three batches as per the commitment	
64.		address of A	Applicant / Marketing der	g	M/s Stallion Pharmaceuticals, PVT, LTD. Plot No. 581, Sundar Industrial Estate, Raiwind Road, Lahore	
	Name,	address of M	Ianufacturing site.		M/s Stallion Pharmaceuticals, PVT, LTD. Plot No. 581, Sundar Industrial Estate, Raiwind Road, Lahore	
	Status	of the applica	ant		 ✓ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver) 	
	Applic of subr		y. No / Tracking ID &	date	Form 5F: SM8-RQZ-RRGJ dated 22-03-2024	
	Details	of fee subm	itted		Rs.30,000/- dated 08-09-2023	
	The proposed proprietary name / brand nar		me	me Stamentin 1000mg Tablet		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit			Each Tablet Contains: Amoxicillin as Trihydrate875mg Clavulanic acid as Potassium Clavulanate 125 mg		
	Pharma	acotherapeuti	c Group of (API)		Antibacterial for systematic use, carbapenem.	
	Refere	nce to Finish	ed product specification	ons	ns USP	
			EVAL	UATI	ION OF DATA	
GMP	status of	the firm		cGMP certificate issued on basis of inspection conducted on 20-09-2022		
Evide	nce of a	oproval of m	anufacturing facility	Firm has submitted letter of issuance of additional section declaring grant of Penicillin (Tablet) section.		
Propo	sed Pacl	x size		6's	6's	
Propo	sed unit	price		As pe	er SRO	
The s	tatus in r	eference reg	ulatory authorities	Appr	roved by US FDA	
For ge	eneric dr	ugs (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 7/1, North West Industrial Zone, Port Qasim, Karachi, Paki Potassium Clavulanate: M/s Zhuhai United Labs (CHI No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhu Guangdong Province, 519040 P.R. China				
Modu	le-II (Qu	ality Overal	l Summary)	Firm	has submitted QOS as per WHO QOS-PD template.	
Module-III Drug Substance:			has submitted detailed drug substance data as per ule 3.2.S.			
		es of Drug S duration of	ubstance Stability studies)		has submitted stability study data of 3 batches of drug tance as per zone IV-A conditions.	
			·			

Tablet.

Module-III Drug Product:

Dissolution Profile

Pharmaceutical Equivalence and Comparative

Firm has submitted data of drug product as per module 3.2.P.

Firm has submitted pharmaceutical equivalence of their product against the innovator's product Augmentin 375mg

		Firm has submitted CDP results of their product against the innovator's product Augmentin 625mg Tablet.		
			ibmitted analytical n bstance as well as dr	nethod validation study reports ug product.
	STABIL	ITY STUI	DY DATA	
API Lot No.	Potassium Cl Amoxicillin		3572301434 23PN3-20023	
Description of Pack (Container closure system)	Aluminium f	oil		
Stability Storage Condition	Real time: 30 Accelerated:		5%±5% RH / 75%±5% RH	
Time Period	Real time: 6 : Accelerated:			
Frequency	Accelerated: Real Time: 0			
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 PROV	IDED ALC	NG WITH STABI	LITY STUDY DATA
Reference of previous approval of a with stability study data of the firm		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).		pharm Firm 1	na. nas submitted Cleara	nercial invoice from M/s Saakh nee certificate issued dated 03- Kg 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 s	ubmitted analytical ı	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)			monitoring of real	lata logger for temperature and time and accelerated stability

Sr.#	Section#	Observation	Firm's response
1.	3.2.P.8.3	Submit stability studies data of 6 th 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		g	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan		
				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 / 7 of submission	Tracking ID &	t date	Form 5F: 9UT-P6P-P161 dated 19-1-2024	
	Details of fee submitted			Rs.75,000/- dated 05-01-2024	
	The proposed proprietary nar	me / brand na	me	KARMOL Suppository	
	Strength / concentration of d Pharmaceutical ingredient (A		:	Each suppository contains: Paracetamol 500mg	
	Pharmacotherapeutic Group	of (API)		Analgesic (ATC code: N02AX02)	
	Reference to Finished produc	ct specification	ons	USP	
		EVAL	UATI	ON OF DATA	
GMP	status of the firm			P certificate issued on basis of inspection conducted on 5-2023	
Evide	nce of approval of manufactur	ring facility	I	Firm has submitted letter of issuance of additional section declaring grant of Suppository section.	
Propo	sed Pack size		1's, 5's, 10's, 20's.		
Propo	sed unit price		As pe	er SRO	
The s	tatus in reference regulatory au	ıthorities	Appr	oved by HPRA of Ireland	
For go	eneric drugs (me-too status)		N/A		
Name	and address of API manufact	urer.	M/s. Pharmagen Private Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore		
Modu	ile-II (Quality Overall Summa	ry)	Firm has submitted QOS as per WHO QOS-PD template.		
Modu	le-III Drug Substance:		Firm has submitted detailed drug substance data as per module 3.2.S.		
	ity Studies of Drug Substance litions & duration of Stability		Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.		
Modu	ile-III Drug Product:		Firm has submitted data of drug product as per module 3.2.P.		
Dissolution Profile		Firm has submitted pharmaceutical equivalence of thei product against the reference product Tipol suppository o Clonmel Healthcare Ltd, Ireland.			
		Firm has submitted analytical method validation study reports for drug substance as well as drug product.			
		STABI	LITY	STUDY DATA	
API I	Lot No.	00510911/2	69/202	23	
Descr	iption of Pack	Aluminium	foil		

(Container closure system)						
Stability Storage Condition		Real time: $5^{\circ}C \pm 3^{\circ}C$ Accelerated: $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$ RH				
Time Period	Real time: 6 months Accelerated: 6 month	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.	
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>:	
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 Applican Authorization Holder	t / Marketing	3	M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan	
	Name, address of Manufacturing site. Status of the applicant			M/s Genix pharma (Pvt) Ltd.Pakistan 44, 45B, Korangi Creek Road, Karachi, Pakistan	
				☑ Manufacturer☐ Importer☐ Is involved in none of the above (contract giver)	
	Application Form Dy. No / Tof submission	Tracking ID &	date	Form 5F: AVG-ZWT-RGQ5 dated 21-02-2024	
	Details of fee submitted			Rs.75,000/- dated 29-01-2024	
	The proposed proprietary nar	me / brand na	me	KARMOL Suppository	
	Strength / concentration of d Pharmaceutical ingredient (A			Each suppository contains: Paracetamol 1000mg	
	Pharmacotherapeutic Group	of (API)		Analgesic (ATC code: N02AX02)	
	Reference to Finished produc	ct specificatio	ns	USP	
		EVAL	UATI	ON OF DATA	
GMP	status of the firm			P certificate issued on basis of inspection conducted on 5-2023	
Evide	nce of approval of manufactur	ing facility	Firm has submitted letter of issuance of additional section declaring grant of Suppository section.		
Propo	sed Pack size		1's, 5's, 10's, 20's.		
Propo	sed unit price		As per SRO		
The st	atus in reference regulatory au	ıthorities	Appr	oved by HPRA of Ireland	
For ge	eneric drugs (me-too status)		N/A		
Name	and address of API manufactor	urer.	M/s. Pharmagen Private Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore		
Modu	le-II (Quality Overall Summa	ry)	Firm has submitted QOS as per WHO QOS-PD template.		
Modu	le-III Drug Substance:		Firm has submitted detailed drug substance data as per module 3.2.S.		
	ity Studies of Drug Substance itions & duration of Stability	studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.		
Modu	le-III Drug Product:		Firm has submitted data of drug product as per module 3.2.P		
Dissolution Profile 1		Firm has submitted pharmaceutical equivalence of the product against the reference product Tipol suppository Clonmel Healthcare Ltd, Ireland.			
•			Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
STABILITY			LITY	STUDY DATA	
API L	API Lot No. 00510911/269/202		59/202	23	
	ription of Pack tainer closure system) Aluminium foil		foil		
Stabili	bility Storage Condition Real time: $5^{\circ}C \pm 3$			°C ± 2°C / 65% ± 5%RH	
Time 1	Period	Real time: 6	montl	18	

	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.	
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>:			
2.	3.2.P.2.2.1				
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. 			

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

Name, address of Manufactu	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 / T of submission	racking ID &	date	Form 5F: V5H-ZTH-U3Y1 dated 12-02-2024		
Details of fee submitted			Rs.30,000/- dated 05-01-2024		
The proposed proprietary nar	ne / brand na	me	KARMOL Suppository		
Strength / concentration of de Pharmaceutical ingredient (A			Each suppository contains: Paracetamol		
Pharmacotherapeutic Group	of (API)		Analgesic (ATC code: N02AX02)		
Reference to Finished produc	et specification	ons	USP		
	EVAL	UATI	ON OF DATA		
GMP status of the firm			P certificate issued on basis of inspection conducted on 5-2023		
Evidence of approval of manufactur	ing facility		has submitted letter of issuance of additional section uring grant of Suppository section.		
Proposed Pack size		1's, 5	5's, 10's, 20's.		
Proposed unit price		As pe	er SRO		
The status in reference regulatory au	ıthorities	Approved by HPRA of Ireland			
For generic drugs (me-too status)		N/A			
Name and address of API manufactu	ırer.	M/s. Pharmagen Private Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore			
Module-II (Quality Overall Summar	ry)	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 s	studies)		has submitted stability study data of 3 batches of drug ance 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 Co Dissolution Profile	mparative	Firm has submitted pharmaceutical equivalence of their product against the reference product Tipol suppository of Clonmel Healthcare Ltd, Ireland.			
Analytical method validation/verific product	cation of	Firm has submitted analytical method validation study reports for drug substance as well as drug product.			
	STABI	LITY STUDY DATA			
API Lot No.	00510911/20	69/202	23		
Description of Pack (Container closure system)	- Alliminilim IAII				
Stability Storage Condition			5°C ± 2°C / 65% ± 5%RH		
Time Period	Real time: 6 Accelerated:				
Frequency	Accelerated: Real Time: (

			T		
Batch No.	23SB-080-01		23SB-081-02	23SB-082-03	
Batch Size	100 supposito	ories	100 suppositories	100 suppositories	
Manufacturing Date	09-2023		09-2023	09-2023	
No. of Batches	03			•	
DOCUMENTS / DATA T	O BE PROV	IDED ALC	ONG WITH STABILIT	Y STUDY DATA	
Reference of previous approval of a with stability study data of the firm (N/A	N/A		
Approval of API/ DML/GMP certification manufacturer issued by concerned reauthority of country of origin.	GMP certificate issued by DRAP Lahore, on basis of inspection conducted on 18-11-2022				
Documents for the procurement of A approval from DRAP (in case of imp	Locally purchased.				
Data of stability batches will be attested respective docum chromatograms, Raw data sheets, Co data sheets etc.	Firm has s	ubmitted analytical reco	rd for product testing.		
Compliance Record of HPLC softwa audit trail reports on product testing	N/A				
Record of Digital data logger for ten humidity monitoring of stability cha time and accelerated)	humidity 1		ogger for temperature and cability studies and manual chambers.		

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: $5^{\circ}C \pm 3^{\circ}C$	
		Accelerated: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$	
		• Justification shall be submitted for the proposed	
		batch size against the number of units required for	
		the complete stability studies till claimed shelf	
		life.	

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 / 7 of submission	Tr J		Form 5F: Z6Z-99G-7G47 dated 19-01-2024			
Details of fee submitted	Details of fee submitted			Rs.30,000/- dated 05-01-2024		
The proposed proprietary na	The proposed proprietary name / brand name		KARMOL Suppository			
Strength / concentration of d Pharmaceutical ingredient (A		:	Each suppository contains: Paracetamol			
Pharmacotherapeutic Group	of (API)		Anal	gesic (ATC code: N02A	X02)	
Reference to Finished produ	ct specification	ons	USP			
	EVAL	UATI	ON O	F DATA		
GMP status of the firm			P certi 5-2023		f inspection conducted on	
Evidence of approval of manufacture	ring facility			bmitted letter of issuan rant of Suppository sect		
Proposed Pack size		1's, 5	s's, 10	's, 20's.		
Proposed unit price		As pe	er SRC)		
The status in reference regulatory as	uthorities	Appr	oved b	by HPRA of Ireland		
For generic drugs (me-too status)		N/A				
Name and address of API manufact	urer.		M/s. Pharmagen Private Limited, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore			
Module-II (Quality Overall Summa	ry)	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			Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.			
Module-III Drug Product:		Firm	has su	bmitted data of drug pr	oduct as per module 3.2.P.	
Pharmaceutical Equivalence and Co Dissolution Profile	omparative	Firm has submitted pharmaceutical equivalence of their product against the reference product Tipol suppository of Clonmel Healthcare Ltd, Ireland.				
Analytical method validation/verific product	cation of	Firm has submitted analytical method validation study reports for drug substance as well as drug product.				
	STABI	LITY	STUL	OY DATA		
API Lot No.	00510911/2	69/202	23			
Description of Pack (Container closure system)	Aluminium	foil	pil			
Stability Storage Condition			C ± 3°C 30°C ± 2°C / 65% ± 5%RH			
Time Period	Real time: 6 month Accelerated: 6 month			nths		
Frequency			0, 3, 6 (Months) 9, 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 T	O BE PROV	IDED 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 certification manufacturer issued by concerned reauthority of country of origin.		GMP certificate issued by DRAP Lahore, on basis of inspection conducted on 18-11-2022	
Documents for the procurement of A approval from DRAP (in case of imp		Locally purchased.	
Data of stability batches will be attested respective docume chromatograms, Raw data sheets, CO data sheets etc.	ents like	Firm has submitted analytical record for product testing.	
Compliance Record of HPLC softwa audit trail reports on product testing	are 21CFR &	N/A	
Record of Digital data logger for ten humidity monitoring of stability cha 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.	

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: $5^{\circ}C \pm 3^{\circ}C$	
		Accelerated: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$	
		• Justification shall be submitted for the proposed	
		batch size against the number of units required for	
		the complete stability studies till claimed shelf	
		life.	

- ➤ 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				
	Status of application	☐ New Drug Product (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			conditions: $C \pm 2^{\circ}C / 65\% \pm 0^{\circ}C \pm 2^{\circ}C / 75\%$			
	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 comparative dissolution profile	and 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/verifical product	cation	on Method verification studies have submitted including linearity, range, accuracy, precision, specificty.				
	STAE	BILITY	Y STUDY DAT	CA			
Manufac	cturer of API		Vision Pharmaceuticals (Pvt.) Ltd Plot No. 22-23, Industrial Friangle, Kahuta Road, Islamabad- Pakistan				
API Lot	No.	DE92	DE929ER				
_	ion of Pack er closure system)	Alu-A	Alu-Alu blister packed in unit carton (1×10's)				
Stability	Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{RH}$				
Time Pe	riod	Real time: 6 months Accelerated: 6 months					
Frequen	1 0		Accelerated: 0,3,6 (Months) Real Time: 0, 3, 6 (Months)				
Batch N	o.	T-00	1	T-002	Т	Γ-003	
Batch Size 2			cap	2500 cap	2	2500 cap	
Manufacturing Date 09-2)21	09-2021	0	9-2021	
Date of 1	Date of Initiation 25-0		9-2021	25-09-2021	2	25-09-2021	
No. of B	No. of Batches			03			
	T		rative Portion				
1.	Reference of previous approva applications with stability study data firm (if any)			g, Datzend 40	mg, prez	zula 75mg,100mg	

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

Remarks of Evaluator:

Observation		
reference regulatory n Board in its 275 th		
)		

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				

Propose	Proposed Pack size		As per SRO		
Propose	Proposed unit price		As per SRO		
The stat	For generic drugs (me-too status)		Diclofenac sodium 100mg Modified Release capsule Approved by HPRA of Ireland		
For gen			Product: Mobikare SR100mg capsules Manufacturer: M/S Barrett Hodgson Pakistan (Pvt) Ltd (Reg No 029393)		
GMP st manufac		ished product	New license granted on 07/06/2021 Tablet, capsule, dry powder and Ampule (General & General Antibiotic) section approved.		
Name a	and address of	API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan		
Module	Module-II (Quality Overall Summary) Module III (Drug Substance) Stability studies Module-III (Drug Product): Pharmaceutical equivalence and comparative dissolution profile		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			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 or specification, reference standard, container closure system and stability studies of drug substance		
Stability			Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 72 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months		
Module			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 & 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 (Road, Islamabad- Pakista			(Pvt.) Ltd Plot No. 22-23, Industrial Triangle, Kahuta an		
API Lot No. DE929ER		DE929ER	_		
_	Description of Pack (Container closure system) Alu-A		n unit carton (1×10's)		
, ,		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Time Period Real time: 6 months		Real time: 6 months			

		Accelerated: 6 months				
Frequency		Accelerated: 0,3, 6 (Months) Real Time: 0, 3, 6 (Months)				
Batch I	No.	T-001	T-002	T-003		
Batch S	Size	2500 cap	2500 cap	2500 cap		
Manufa	acturing Date	10-2021	10-2021	10-2021		
No. of	Batches		03			
		Administrat	ive Portion			
1.		s approval of applications at a of the firm (if any)	N/A			
2.	* *	issued by concerned by	Copy of GMP certificate No. F.3-26/2019 DRAP issued by DRAP valid till 09/05/2022.			
3.	Documents for the p approval from DRAP	rocurement of API with (in case of import).	Local purchase from Vision	on Pharma Islamabad.		
4.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		e			
5.	. Compliance Record of HPLC software 21CFR & audit trail reports on product testing		R N/A			
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)					

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				
	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 $\beta 2$ -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 WH	IO QOS-PD template.			
	Module-III Drug Substance:	Firm has submitted detailed drug su	bstance 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 pro	duct 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.				
	S	TABILITY STUDY DATA				
Manı	ufacturer of API	Fluticasone Furoate: VAMSI LAE Umeclidinium Bromide: Inke, S.A Vilanterol Trifenatate: Inke, S.A.				
API l	Lot No.	Fluticasone Furoate: FTF (P)-0010121 Umeclidinium Bromide: PP-15M Vilanterol Trifenatate: P-12M				
	ription of Pack tainer closure system)	60's Capsules packed in unit carton along with leaflet.				
Stabi	lity Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH				
Time	Period	Real time: 6 months Accelerated: 6 months				
Frequ	uency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 8, 12, 16, 18, 24 (Months)				
Batcl	h No.	FVL-001	FVL-002			
Batcl	h Size	Capsule 1: 5000 Capsules Capsule 2: 5000 Capsules	Capsule 1: 5000 Capsules Capsule 2: 5000 Capsules			

Manufacturina Data			00 202	12		0.	2002
Manufacturing Date Date of Initiation		08-2023				8-2023	
No. of Batches		15-08-2023 15-08-2023 02					-08-2023
NO. (of Batches	Administr	rativa Da	rtion		J2	
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Administrative Portion 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					
2.	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	<u> </u>					
3.	Documents for the procurement of API with approval from DRAP (in case of import).		bmitted.		e approve	ed by DRAP a	attested by AD I&E,
		Batch	No.	Invoice No.		Quantity Imported	
		FTF (P)-0	010121	EXP/0	5/21-22	50 grams	30-Sep-2021
		Umeclidin	ium Bron	nide:			
		Batch No.	Compu d N			iantity ported	Date of approval by DRAP
		PP-15M HORIZONO 122021		ON02	NO2 50 grams		17-Sep-2021
		Vilanterol Trifenatate:					
		Batch No. Computerized		ıterized		Quantity Imported	Date of approval by DRAP
		P-12M	HORIZA 1	ON0212	2202	50 grams	17-Sep-2021

4.	1	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	
6.		Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.

Remarks of Evaluator $^{\rm II}$:

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.

2. 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

Pharmaceutical form of applied drug	DPI (Dry Powder Inhaler) Capsule	
Pharmacotherapeutic Group of (API)	Fluticasone furoate is an inhaled corticosteroid that can be used a 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, ar vilanterol inhalation powder) for oral inhalation use" (US-FD 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 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 3.2.9	
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substant 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, Aerodynam particle size distribution and Microbial Test. As the applied druproduct is Dry Powder inhaler Capsule for inhalational use, So CD is not required.	
Analytical method validation/verification of product	Analytical method verification studies of both drug substances ar Analytical Method Validation Studies have been submitted includin Introduction, Verification/Validation of Assay method, Specificit Accuracy, Precision, Linearity concentration and peak range.	
S	TABILITY STUDY DATA	
facturer of API	Fluticasone Furoate: VAMSI LABS LTD. Umeclidinium Bromide: Inke, S.A.	

		Vilanterol Trifenat	ate: Inke, S.A.		
API	Lot No.	Fluticasone Furoate: FTF (P)-0010121 Umeclidinium Bromide: PP-15M Vilanterol Trifenatate: P-12M			
	ription of Pack tainer closure system)	60's Capsules packed in unit carton along with leaflet.		t.	
Stabi	ility Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm$			
Time	e Period	Real time: 6 months Accelerated: 6 mont			
Freq	uency	Accelerated: 0, 3, 6 Real Time: 0, 3, 6, 8		Months)	
Batc	h No.	FVL-00	01	FVL	L-002
Batc	h Size	Capsule 1: 5000 Capsule 2: 5000	•		000 Capsules 000 Capsules
Man	ufacturing Date	08-202	23	08–	2023
No. o	of Batches		(02	
		Administrative Po	rtion		
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:			
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).	Copy of Clearance Certificate approved by DRAP attested by AD I&E,			
		B. 1. N		Quantity	Date of
		Batch No.	Invoice No.	Imported	approval by DRAP

Umeclidinium Bromide: Date of Computerize **Batch** Quantity approval by No. d No. **Imported DRAP** PP-15M HORIZON02 50 grams 17-Sep-2021 122021 Vilanterol Trifenatate: Date of **Quantity** Batch Computerized No. approval by No. **Imported DRAP** HORIZON0212202 17-Sep-2021 P-12M 50 grams 4. Data of stability batches will be Data of stability batches supported by attested respective documents supported by attested respective like chromatograms, Raw data sheets, COA, summary data sheets have documents like chromatograms, been submitted. Raw data sheets, COA, summary data sheets etc. of HPLC Submitted Compliance Record software 21CFR & audit trail reports on product testing. Record of Digital data logger for 6. Firm has submitted record of Digital data logger for temperature and temperature and humidity humidity monitoring of stability chambers. monitoring of stability chambers (real time and accelerated) 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. Name, address of Applicant / M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial **Marketing Authorization Holder** Estate, Taxila, Pakistan. Name, address of Manufacturing M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan Status of the applicant ☐ 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 □ Domestic sale product ☐ Export sale ☐ Domestic and Export sales

Evidence of approval of required manufacturing facility	Firm has submitted copy of section approval letter issued by Secretar 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 cGMI 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 long-acting and selective sympathomimetic beta-receptor agonist v 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. Summarize 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 drugsubstance, Reference standard or materials container closure system	

1		and stability studies of both drug subs	tances		
	Stability studies	and stability studies of both drug substances. Stability study conditions: Fluticasone Propionate Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 48 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months Salmeterol Xinafoate: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 60 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months			
Module-III (Drug Product): The firm has submitted detail of Drug Products including Descand composition of drug product, Pharmaceutical Develor Manufacturing process development, Microbiological attrive Manufacturer, Master formulations, Description of Manufacturer, Process and Process Controls, Control of Critical Step Intermediates, Process Validation and/ or Evaluation, Contexting Excipients with specification and Analytical methods, Control of Products including Finished product specifications and test movalidation of Analytical methods, Batch analysis, reference st Container closure and stabilities studies.			Pharmaceutical Development, at, Microbiological attribution, Description of Manufacturing ontrol of Critical Steps and and/ or Evaluation, Control of lytical methods, Control of Drug specifications and test methods, ch analysis, reference standard,		
	Pharmaceutical equivalence	Pharmaceutical Equivalence have Reference product that is Seretide Dis 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		21			
	cription of Pack ntainer closure system)				
(COI	•				
	ility Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RF Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$			
Stab	•				
Stab	ility Storage Condition	Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ Real time: 6 months			
Stab Time Freq	ility Storage Condition	Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ Real time: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Months)			
Time Freq Batc	e Period uency	Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ Real time: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	RH		
Time Freq Batc	e Period uency h No.	Accelerated: 40°C ± 2°C / 75% ± 5% 1 Real time: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) FSM-001	FSM-002		
Time Freq Batc Batc Man	ility Storage Condition e Period uency h No. h Size	Accelerated: 40°C ± 2°C / 75% ± 5% 1 Real time: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) FSM-001 5000 Capsules 01– 2023	FSM-002 5000 Capsules 01–2023		
Time Freq Batc Batc Man	ility Storage Condition e Period uency h No. h Size ufacturing Date	Accelerated: 40°C ± 2°C / 75% ± 5% 1 Real time: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) FSM-001 5000 Capsules 01–2023	FSM-002 5000 Capsules 01–2023		
Time Freq Batc Batc Man	ility Storage Condition e Period uency h No. h Size ufacturing Date of Batches Name, address of Applicant /	Accelerated: 40°C ± 2°C / 75% ± 5% 1 Real time: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) FSM-001 5000 Capsules 01– 2023 02 M/s Horizon Healthcare (Pvt.) Ltd.	FSM-002 5000 Capsules 01–2023 Plot no. 35-A, Small Industrial		
Time Freq Batc Batc Man	ility Storage Condition e Period uency h No. h Size ufacturing Date of Batches Name, address of Applicant / Marketing Authorization Holder Name, address of Manufacturing	Accelerated: 40°C ± 2°C / 75% ± 5% 1 Real time: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) FSM-001 5000 Capsules 01– 2023 02 M/s Horizon Healthcare (Pvt.) Ltd. Estate, Taxila, Pakistan. M/s Horizon Healthcare (Pvt.) Ltd.	FSM-002 5000 Capsules 01–2023 Plot no. 35-A, Small Industrial , Taxila, Pakistan		

Intended use of pharmaceutical product	l ⊠ 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 Secret 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 cG 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 long-acting and selective sympathomimetic beta-receptor agonist v 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 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. Summari information related to structure, general properties, Manufacture description of manufacturing process and controls, Characterizati Impurities, Specifications, Analytical procedures, Validation analytical procedure, batch analysis and justification of specificative reference standard, container closure system and stability studies both drug substances and drug product is submitted.	

	Name, address of Manufacturing site. Status of the applicant	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, ☑ Manufacturer	Taxila, Pakistan	
75.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt.) Ltd. Estate, Taxila, Pakistan.	Piot no. 35-A, Small Industrial	
	of Batches Name address of Ambigunt /	M/s Havinan Haalthaans (Dut.) Ltd.	District 25 A Consult 1 4 1 1	
	ufacturing Date	01–2023	01–2023	
	h Size	5000 Capsules	5000 Capsules	
Batc	h No.	FSH-001	FSH-002	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Time	e Period	Real time: 6 months Accelerated: 6 months		
	ntainer closure system) ility Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% RF Accelerated: 40°C ± 2°C / 75% ± 5% I		
	cription of Pack	30's Capsules packed in unit carton al	ong with leaflet.	
API	Lot No.	Fluticasone Propionate: FTP-012082 Salmeterol Xinafoate: SX-0070721	21	
		STABILITY STUDY DATA		
	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.		
	Pharmaceutical equivalence	Pharmaceutical Equivalence have been established against t Reference product that is Seretide Diskus 500mcg/50mcg (Powder Inhalation) of GSK		
Module-III (Drug Product):		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 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.		

	☐ Importer	
Ctatus of annication	☐ Is involved in none of the above (contract giver)	
Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)	
Intended use of pharmaceutical	☑ Domestic sale	
product	☐ Export sale	
	☐ Domestic and Export sales	
Evidence of approval of required manufacturing facility	Firm has submitted copy of section approval letter issued by Secretar 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 cGM 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	Each capsule contains:	
Active Pharmaceutical ingredient	Fluticasone Propionate 100mcg	
(API) per unit	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)	
Oharmaaautiaal form of annliad	 	
Pharmaceutical form of applied drug	DPI (dry powder Inhaler) Capsule	
Pharmacotherapeutic Group of	Budesonide Belongs to Glucocorticoids, and Formoterol Fumarate is	
(API)	long-acting and selective sympathomimetic beta-receptor agonist wi bronchodilator activity.	
Reference to Finished product	As per innovator's specs.	
specifications	As per limovator s spees.	
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 ar 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.	An ISO-9001-2015 and WHO-GMP Company	
	A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA).	
	Formoterol Fumarate: VAMSI LABS LTD.	
	Formoterol Fumarate: VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company	
	Formoterol Fumarate: VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra	
Module-II (Quality Overall	Formoterol Fumarate: VAMSI LABS LTD. An ISO-9001-2015 and WHO-GMP Company A-14/15, MIDC Area, Chincholi, Solapur-413255, Maharashtra (INDIA).	

		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.		
Stability studies Module-III (Drug Product):		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 study conditions: Fluticasone Propionate Real time: $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$ RH for 48 months Accelerated: $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%$ RH for 6 months Salmeterol Xinafoate: Real time: $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$ RH for 60 months Accelerated: $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%$ RH for 6 months		
		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		
validation/verification of product Analytical Method Introduction, Veri		Analytical Method Validation Studies Introduction, Verification/Validation	cal method verification studies of both drug substances and cal Method Validation Studies have been submitted including ction, Verification/Validation of Assay method, Specificity, cy, 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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Freq	uency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batc	h No.	FSL-001	FSL-002	
Batc	h Size	5000 Capsules	5000 Capsules	
Man	ufacturing Date	01–2023	01–2023	
No.	of Batches	02		
		Administrative Portion		
_	· · · · · · · · · · · · · · · · · · ·		· · · · · · · · · · · · · · · · · · ·	

Reference of previous approval of Firm has referred to onsite inspection report of this product: applications with stability study data of the firm (if any) 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. ii. 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. GMP certificate of M/s VAMSI LABS LTD. is submitted, issued by FDA Approval of API/DML/GMP certificate of API manufacturer valid upto: 04-10-2024 issued by concerned regulatory authority of country of origin. Documents for the procurement of Copy of Clearance Certificate approved by DRAP attested by AD I&E, has API with approval from DRAP (in been submitted. case of import). **Fluticasone Propionate:** Date of Quantity Batch No. Invoice No. approval by **Imported DRAP** EXP/210/21-SX-0070721 25.00 grams 29-Aug-2022 22 **Salmeterol Xinafoate:** Date of Quantity Batch No. Invoice No. approval by **Imported** DRAP FTP-EXP/210/21-22 25.00 grams 29-Aug-2022 0120821 Data of stability batches will be Data of stability batches supported by attested respective documents like supported by attested respective chromatograms, Raw data sheets, COA, summary data sheets have been documents like chromatograms, submitted. Raw data sheets, COA, summary data sheets etc. Compliance Record of HPLC Compliance Record of HPLC software 21CFR & audit trail reports on software 21CFR & audit trail product testing have been submitted. reports on product testing. Record of Digital data logger for Firm has submitted record of Digital data logger for temperature and temperature and humidity humidity monitoring of stability chambers. monitoring of stability chambers

(real time and accelerated)

Remarks of Evaluator II:

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

- 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 re	gulatory authorities	Miorel 4mg/2ml , solution for injection (IM) in ampoule, approved by, ANSM France.	
For generic drugs (me-too	o status)	Muscoril 4mg/2ml Injection Reg. No. 015501 M/s Sanofi Aventis Pkaistan	
Name and address of API	I manufacturer.	M/s Dr. Willmar Schwabe India Pvt. Ltd. Plot No. 51-53. Sector 31-B IMT Rohtak Haryana India.	
Module-II (Quality Overa	all 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 Substan	ce:	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 (Conditions & duration of		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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 Equival Dissolution Profile	ence and Comparative	Firm has submitted pharmaceutical equivalence of their product against the Muscoril injection.	
Analytical method va	alidation/verification of	Firm has submitted analytical method validation study reports for drug substance as well as drug product.	
	STABILITY STU	UDY DATA	
Manufacturer of API	M/s Dr. Willmar Schwab Plot No. 51-53. Sector 31	e India Pvt. Ltd. -B IMT Rohtak Haryana India.	
API Lot No.	WS-HH/THIO/22020006	5	

	ription of Pack tainer closure system)	Liquid solution filled in glass ampoules				
Stabi	ility Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time	e Period	Real time: 6 months Accelerated: 6 months				
Freq	uency	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 / DAT	TA TO BE PROVIDED AL	ONG WITH STABILITY	Y STUDY DATA		
1.	Reference of previous apstability study data of the	firm (if any) Firm has been inspected for verification of stable study data for following products. a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285 th meeting of		oducts.		

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 285 th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288 th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290 th 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.
		·

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

- 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	M/s Seraph Pharmaceutical Plot # 210, Industrial	
	Authorization Holder	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.

			of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} \ / \ 75\% \pm 5\%$ RH. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} \ / \ 65\%$ $\pm 5\%$ RH		
	Module-III Drug Produc	t:	Firm has submitted data of drug product included description, composition, pharmaced development, manufacture, manufacturing product and process control, process validation protection of excipients, control of drug prospecifications, analytical procedures, validation analytical procedures, batch analysis, justificat specifications, reference standard or matecontainer closure system and stability.		
	Pharmaceutical Equiva Dissolution Profile	lence and Comparative		s submitted pharmaceutical equivalence of oduct against the innovator's product.	
	Analytical method v product	alidation/verification of	Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
		STABILITY STUDY DATA			
Man			i Shuangda Pharmaceutical Co., Ltd. Zone , Pingyuan County, Dezhou City, Shandong		
API	Lot No.	028221101	8221101		
	ription of Pack tainer closure system)	Liquid solution filled in	glass ampoules		
Stabi	ility Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Time	e Period	Real time: 6 months Accelerated: 6 months			
Frequ	uency	Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mont			
Batcl	h No.	T001		T002	
Batcl	h Size	2000 ampoules		2000 ampoules	
Man	ufacturing Date	01-2023		01-2023	
Date	of Initiation	01-01-2023		01-01-2023	
No. o	of Batches		02		
	DOCUMENTS / DATA	A TO BE PROVIDED A	LONG W	/ITH STABILITY STUDY DATA	
1.	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 285 th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288 th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290 th meeting of Registration Board.		
2.	2. Approval of API/ DML/GMP certificate of API		Firm has submitted copy of GMP Certificate This		

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.	
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.	0 00 1	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Re	marks of Evaluator:	

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

	T		
	The status in reference re	gulatory authorities	Ibandronate sodium 3mg/3ml injection approved by US FDDA as pre-filled syringe.
	For generic drugs (me-to-	o status)	Adronil Injection 3mg/3ml of M/s Searle Company Limited, Pakistan (Reg.No. 075870)
	Name and address of AP	I manufacturer.	M/s PROVENTUS LIFE SCIENCES PVT., LTD No. C-9, Industrial complex, Maraimalai Nagar-603209,Kancheepuram District.
	Module-II (Quality Overa	all 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 Substan	ce:	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 (Conditions & duration o		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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 Analytical method validation/verification of product		Firm has submitted pharmaceutical equivalence of their product against the Adronil injection.
			Firm has submitted analytical method validation study reports for drug substance as well as drug product.
		STABILITY ST	UDY DATA
Manufa	acturer of API		SCIENCES PVT., LTD No. C-9, Industrial complex, 99, Kancheepuram District.
API Lo	ot No.	IBB09221009	
	otion of Pack iner closure system)	Liquid solution filled in §	glass ampoules
	<u>.</u>	l	

Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	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

on of stability
8 th meeting of 0 th meeting of
cate issued by 2024.
certificate no. or Ibandronic
product
R compliance rail report for
ata logger for real time and

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

- 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: Nepafenac1mg		
	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) Stability studies Module-III (Drug Product):		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		
			Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$. 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 equiva dissolution profile	alence and comparative		eutical Equivalence have been established Opthalmic suspension.	
	Analytical method v product	validation/verification of		validation studies have submitted including y, precision, specificity.	
		STABILITY S	TUDY D	ATA	
Manu	facturer of API	M/s Precise Bio-Pharma Manufacturing: C 384, T 703, Maharashtra, INDIA	TC Industrial Area, Pawane MIDC, Navi Mumbai - 400		
API L	ot No.	075005062022.			
	iption of Pack ainer closure system)	LDPE bottle with polypro	opylene d	ropping nozzle with HDPE Cap.	
Stabil	ity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	ency	Accelerated: 0,3,6 (Mort Real Time: 0,3,6 (Mont)	,		
Batch	No.	T01		T02	
Batch	Size	2,000 packs		2,000 packs	
Manu	facturing Date	05-2023		05-2023	
No. of	f Batches		02		
	Administrati		ive Porti	on	
1.	1. Reference of previous approval of applications with stability study data of the firm (if any)		Not Applicable		
2.			Firm has submitted copy of DML no. MH/104764 issued by FDA Maharashtra India valid till 05-09-2027.		
3.	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.		

	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	N/A
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

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

- 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.

	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 M/s Cunningham Pharmaceuticals (Pvt.) Limited Plot No. 81- Sundar Industrial Estate, Raiwind road, Lahore		
	Name, address of Manufacturing site.			
	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-t	oo status)	N/A
Name and address of A	PI manufacturer.	M/s Yibin Hongguang Pharmaceutical Co. Ltd Luolong Street, Nanxi District Yibin, Sichuan, 644002 China.
Module-II (Quality Ove	erall 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 Subst	ance)	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 \pm 3 °C). The real time stability data is conducted at (-20°C \pm 5°C).
Module-III (Drug Produ	uct):	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 equiva	alence and comparative	Pharmaceutical Equivalence have been established Rhopressa eye drops of M/s Alcon.
Analytical method v	validation/verification of	Method validation studies have submitted including accuracy, precision, specificity.
	STABILITY S	TUDY DATA
Manufacturer of API M/s Yibin Hongguang Ph Luolong Street, Nanxi Di		narmaceutical Co. Ltd strict Yibin, Sichuan, 644002 China.
API Lot No. MS104901-230101		
Description of Pack (Container closure system) LDPE bottle with polypro		opylene dropping nozzle with HDPE Cap.
Stability Storage Condition	Real time: 5°C ± 3°C Accelerated: 25°C ± 2°C	;40% RH <u>+</u> 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		Т02	
Batch	Size	2,000 packs		2,000 packs	
Manu	facturing Date	05-2023		05-2023	
No. of	f Batches			02	
		Administrati	ve Porti	on	
1.	Reference of previous with stability study data	approval of applications of the firm (if any)		Not Applicable	
2.	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.				
5.	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)					

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	
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. 	

- 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	M/s Cunningham Pharmaceuticals (Pvt.) Limited
	Authorization Holder	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: Latanoprost0.05mg Timolol as Maleate5mg
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, Distri Raigad, Maharashtra State, India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-P template. Summarized information related nomenclature, structure, general properties solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities specifications, analytical procedures and verification, batch analysis and justification specification, reference standard, container closures system and stability studies of drug substance and drug substance and drug substance and drug substance.

		product is submitte	ed.	
Module III (Drug Subst	rance)	general properties manufacturers, de- and controls, speci- its verification, b specification, refe	ted detail of nomenclature, structure, es, solubilities, physical form, scription of manufacturing process fications, analytical procedures and atch analysis and justification of trence standard, container closure y studies of drug substance	
Stability studies			d stability study data of 3 batches of es at both accelerated as well as real	
		Latanoprost: The accelerated stability data is conducte at $5^{\circ}C \pm 3^{\circ}C / 75\% \pm 5\%$ RH. The real time stability data is conducted at $-20^{\circ}C \pm 5^{\circ}C$. Timolol maleate: The accelerated stability data is conducted at $40^{\circ} \pm 2^{\circ}C / 75\% \pm 5\%$ RH. The real time stability data is conducted at $30^{\circ}C + 2^{\circ}C / 65 \pm 5\%$ 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 equivadissolution profile	Pharmaceutical equivalence and comparative dissolution profile		Pharmaceutical Equivalence have been established Xalacom eye drops of M/s Pfizer.	
Analytical method v	validation/verification of	Method validation studies have submitted including accuracy, precision, specificity.		
	STABILITY S	TUDY DATA		
Timolol Maleate: M/s FDC Limited, Plot N		277 11 Neratovice, Czech Republic		
API Lot No.	Latanoprost: 2008S004. Timolol: 021D026	Latanoprost: 2008S004.		
Description of Pack (Container closure system)	LDPE bottle with polypropylene dropping nozzle with HDPE Cap.		ozzle with HDPE Cap.	
Stability Storage Condition	Real time: $5^{\circ}C \pm 3^{\circ}C$ Accelerated: $25^{\circ}C \pm 2^{\circ}C;40\%$ RH $\pm 5\%$			
Time Period Real time: 24 months Accelerated: 6 months				
Frequency	Frequency Accelerated: 0 , 3,6 (Mo Real Time: 0 , 3,6 (Month			
Batch No.	T01		T02	
Batch Size	2,000 packs		2,000 packs	
Manufacturing Date	11/2022		11/2022	
No. of Batches		02		

	Administrat	ive 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
Rema	rks of Evaluator:	
	proposed shelf life and on accelerated studies the registration application.	on batches on long term stability studies throughout for six months as per the commitment submitted in on of first three batches as per the commitment 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 Latanoprost0.05 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-P template. Summarized information related nomenclature, structure, general properties solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities specifications, analytical procedures and verification, batch analysis and justification specification, reference standard, container closury system and stability studies of drug substance and drup product is submitted.
Module III (Drug Substance)	The firm as submitted detail of nomenclature, structur general properties, solubilities, physical formanufacturers, description of manufacturing proce and controls, specifications, analytical procedures at its verification, batch analysis and justification specification, reference standard, container closur system and stability studies of drug substance
Stability studies	Firm has submitted stability study data of 3 batches drug substance at both accelerated as well as real tin conditions. The accelerated stability data is conducted at $5^{\circ}\text{C} \pm 3^{\circ}\text{C} / 75\% \pm 5\%$ RH. The real time stabilidata is conducted at $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$.
Module-III (Drug Product):	The firm has submitted detail of manufacturer description of manufacturing process and control impurities, specifications, analytical procedure and inverification studies, batch analysis and justification
	specification, reference standard, container closu system and stability studies of drug product.

	product		accuracy, precision, specificity.		
		STABILITY S	TUDY DATA		
Manufacturer of API		M/s Cayman Pharma. Address: ul. Práce 657, 2	277 11 Neratovice, (Czech Republic	
API I	Lot No.	2008S004.			
	ription of Pack tainer closure system)	LDPE bottle with polypro	opylene dropping no	ozzle with HDPE Cap.	
Stabil	lity Storage Condition	Real time: $5^{\circ}C \pm 3^{\circ}C$ Accelerated: $25^{\circ}C \pm 2^{\circ}C$;40% RH <u>+</u> 5%		
Time	Period	Real time: 24 months Accelerated: 6 months			
Frequ	iency	Accelerated: 0, 3,6 (Mo Real Time: 0, 3,6 (Mont			
Batch	ı No.	T001		T002	
Batch	Size	2,000 packs		2,000 packs	
Manu	facturing Date	09/2022		09/2022	
No. o	f Batches	02			
	_	Administrat	ive Portion		
1.	Reference of previous with stability study data	approval of applications a of the firm (if any)	Not Applicable		
2.		by concerned regulatory		d copy of EUdra GMP certificate no. 2" valid till 27-07-2025.	
3.	Documents for the p approval from DRAP (i	rocurement of API with in case of import).	Firm has submitte from Pacific Pharr With copy of ADC	d loan letter of Latanoprost 3.5gm naceuticals Ltd., dated: 12-08-2022 attested commercial invoice dated: ne of Pacific Pharmaceuticals Ltd. 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 audit trail reports on pro	HPLC software 21CFR & oduct testing		N/A	
6.		logger for temperature and of stability chambers (real		Submitted	
Rema	arks of Evaluator:				

- 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.

33.	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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$.		
	Module-III (Drug Produ	uct):	The firm has submitted d description of manufacturing impurities, specifications, and verification studies, batch and specification, reference stan system and stability studies of	g process and controls, llytical procedure and its llysis and justification of dard, container closure	
	Pharmaceutical equivadissolution profile	alence and comparative	Pharmaceutical Equivalence & submitted against Xanax 0.25		
	Analytical method v	validation/verification of	Method validation studies has accuracy, precision, specificit	•	
		STABILITY S	TUDY DATA		
Manu	facturer of API	M/s Lake Chemicals Pri Taluk, Bangalore-562107	vate Limited., 21-M, Attibele , Karnataka (India).	Industrial Area, Anekal	
API L	ot No.	802022003A.			
	iption of Pack ainer closure system)	Aluminum / Aluminum b	blister		
Stabil	ity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60^{\circ}$			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	ency	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	
Manu	facturing Date	11/2022.	11/2022.	11/2022.	
No. of	f Batches		02		
		Administrat	ive Portion		
1.	Reference of previous with stability study data	approval of applications a of the firm (if any)	Not Appli	cable	
2.	* *	by concerned regulatory	Firm has submitted valid CEI 2008-229 - Rev 03 issued by in name of M/s Lake Chemica	EDQM for bromaxepam	
3.	Documents for the paper approval from DRAP (i	rocurement of API with n case of import).	Firm has submitted Lic 3146642849182 issued by 13-04-2022 along with import of 38gm of Alpraz Firm has submitted letter (M-307) dated 09-09-202 (Reg-I) for approval by allocation of control Alprazolam.	y AD I&E Lahore dated commercial invoice for olam no. F.5-2/2021-REG-II from Assistant Director Registration Board for	

		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

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

- 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

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Bromazepam3mg Pharmaceutical form of applied drug Reference to Finished product specifications Proposed Pack size As per SRO Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Azonil 3 mg tablet of M/s Global (Reg.#041540) Name and address of API manufacturer. Module-II (Quality Overall Summary) Module-II (Quality Overall Summary) Module-III (Quality Overall Summary) Module-III (Drug Substance) Module III (Drug Substance) Module III (Drug Substance) Stability studies Module-III (Drug Product): The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical procedures and its verification, batch analysis and justification of specification, analytical procedures and its verification of manufacturing process and controls, specifications, analytical procedures and its verification of manufacturing process and controls, specification, analytical procedures and its verification of manufacturing process and controls, specification, analytical procedures and its verification of manufacturing process and controls, specification, analytical procedures and its verification of manufacturing process and controls, specification, analytical procedures and its verification of manufacturing process and controls, specification, analytical procedures and its verification of specification, reference standard, container closure system and stability study data of 3 batches of drug substance and swell as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5%. Module-III (Drug Product): The firm has submitted detail of manufacturers, description of manufacturers, description of manufacturers, description of manufacturers, descri		The proposed proprietar	ry name / brand name	Bromlet 3mg Tablet	
Pharmacotherapeutic Group of (API) Anxiolytic.					
Reference to Finished product specifications Proposed Pack size As per SRO Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Module-II (Quality Overall Summary) Module-II (Quality Overall Summary) Module-II (Quality Overall Summary) Module III (Drug Substance) Module III (Drug Substance) Module III (Drug Substance) Stability studies Stability studies Module-III (Drug Product): Module-III (Drug		Pharmaceutical form of	applied drug	Tablet	
Proposed Pack size Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Azonil 3 mg tablet of M/s Global (Reg.#041540) Azonil 3 mg tablet of M/s Lake Chemicals Private Limited, 21-M, Attibele Industrial Area, Anekal Taluk, Bangalore-562107, Karnataka (India).		Pharmacotherapeutic Gr	roup of (API)	Anxiolytic.	
Proposed unit price As per SRO		Reference to Finished p	roduct specifications	Innovator's Specifications.	
The status in reference regulatory authorities For generic drugs (me-too status) 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) Module-II (Quality Overall Summary) Module-III (Drug Substance) Module III (Drug Substance) The firm as submitted detail of 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 at both accelerated as well as real time conditions. The accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% Rt. 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 manufacturers, description of manufacturing process and controls, simpurities, specification, reference standard, container closure system and stability studies of drug gubtata is conducted at 40°C ± 2°C / 75% ± 5%. The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specification, reference standard, container closure system and stability studies of drug product. Pharmaceutical equivalence and comparative pharmaceutical equivalence & CDP studies have been submitt		Proposed Pack size		As per SRO	
For generic drugs (me-too status) 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) 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, batch analysis and justification of specification, substance and stability studies of drug substance at both accelerated as well as real time conditions. The accelerated at sability 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 40°C ± 2°C /75% ± 5% EM. The real time stability data is conducted at 40°C ± 2°C /75% ± 5% the firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specification, 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 Analytical method validation/verification of method validation studies hate submitted including accelerated as procedures, precision, specificity. STABILITY STUD		Proposed unit price		As per SRO	
Name and address of API manufacturer. M/s Lake Chemicals Private Limited., 21-M, Attibele Industrial Area, Anekal Taluk, Bangalore-562107, Karnataka (India).		The status in reference i	regulatory authorities	Approved by HPRA of Ireland	
Module-II (Quality Overall Summary)		For generic drugs (me-t	oo status)	Azonil 3 mg tablet of M/s Global (Reg.#041540)	
Lemplate. 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)		Name and address of A	PI manufacturer.	Industrial Area, Anekal Taluk, Bangalore-562107,	
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 studies Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$. 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 Analytical method validation/verification of product STABILITY STUDY DATA Manufacturer of API M/s Lake Chemicals Private Limited., 21-M, Attibele Industrial Area, Anekal Taluk, Bangalore-562107, Karnataka (India).		Module III (Drug Substance) To p p p junt of the p p p p junt of the p p p p junt of the p p p p p p p p p p p p p p p p p p p		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	
drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$. 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 Analytical method validation/verification of product STABILITY STUDY DATA Manufacturer of API M/s Lake Chemicals Private Limited., 21-M, Attibele Industrial Area, Anekal Taluk, Bangalore-562107, Karnataka (India).				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	
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 Analytical method validation/verification of product STABILITY STUDY DATA Manufacturer of API M/s Lake Chemicals Private Limited., 21-M, Attibele Industrial Area, Anekal Taluk, Bangalore-562107, Karnataka (India).		Stability studies		drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. The real time stability	
dissolution profile submitted against Lexotanil 3mg tablet. Analytical method validation/verification of product 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).		Module-III (Drug Product):		description of manufacturing process and controls impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure	
product 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).			alence and comparative		
Manufacturer of API M/s Lake Chemicals Private Limited., 21-M, Attibele Industrial Area, Anekal Taluk, Bangalore-562107, Karnataka (India).		•	validation/verification of	~ I	
Taluk, Bangalore-562107, Karnataka (India).			STABILITY ST	TUDY DATA	
API Lot No. 802022003A.	Manuf	Cacturer of API			
	API L	ot No.	802022003A.		

	Description of Pack (Container closure system) Aluminum /		Aluminum / Aluminum b	num blister			
Stabili	Stability Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65^{\circ}$						
Time I	Period		Real time: 6 months				
			Accelerated: 6 months				
Freque	ency		Accelerated: 0, 3, 6 (Monte Real Time: 0, 3, 6 (Monte				
Batch	No.	Т	7001	T002		T003	
Batch	Size	5	,000 Tablets	5,000	Tablets	5,000 Tablets	
Manuf	facturing Date	1	1/2022.	11/20)22.	11/2022.	
No. of	Batches				02		
			Administrat	ive Po	rtion		
1.		•	pproval of applications f the firm (if any)		Not Appli	cable	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			2010-	has submitted valid CE 053 - Rev 00 issued by ne of M/s Lake Chemica	EDQM for Broma	azepam
3.	Documents for the procurement of API with approval from DRAP (in case of import).			3 1 1 iii F (1) (2) a B 7 g	irm has submitted Lic 146642849182 issued b 3-04-2022 along with apport of 58gm of Broma irm has submitted lette M-307) dated 09-09-202 Reg-I) for approval by llocation of control romazepam. Firm has submitted lette 7) dated 13-12-2021 from ranting import authorizated for 58gm of Bromaze	y AD I&E Lahor commercial involved involved involved in the commercial invo	e dated ice for REG-II Director ard for cluding CD (M-D) (CD)
4.	attested chromatogran	respective ns,	will be supported by documents like mmary data sheets etc.		Submit	ted	
5.	Compliance I audit trail rep		PLC software 21CFR & uct testing		N/A		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)						
Rema	rks of Evalua	tor:					
	Section #	Observation			Firm's response		
	verification studies for			ethod drug	Submitted		
	 substance by M/s Cunningham 3.2.P.6 COA of reference/working states used for analysis of stability bases about the substituted. 				Submitted		
1	shall be submitted.						

3.2.P.8.3	•	Submit	complete	batch	Submitted	
		manufactu	ring record of	stability		
		batches.				
	•	Submit red	cord of digital da	ta logger		
		for temp	perature and	humidity		
		monitoring	g of stability o	chambers		
		(real time	and accelerated)			

- 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 Ceftizoxime1gm		
	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 AP	I manufacturer.	Akum Life Sciences Limited Unit I: VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)	
Module-II (Quality Overa	all Summary)	Firm has submitted QOS as per WHO QOS-PI 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 it validation, batch analysis and justification 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 (Conditions & duration o		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH f The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\%$ $\pm 5\%$ 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 Equival Dissolution Profile	ence and Comparative	Firm has submitted pharmaceutical equivalence of their product against the Cefizox 1g manufactured by Barretee Hodgson Pakistan Pvt Lt	
Analytical method va	alidation/verification of	Firm has submitted analytical method validation study reports for drug substance as well as drug product.	
	STABILITY STU	UDY DATA	
Manufacturer of API	Akum Life Sciences Lim Unit I: VIII, Sundran, Punjab-140 201 (India)	nited P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali,	
API Lot No.	CFS/003/17, CFS/005/17	7, CFS/007/17	
Description of Pack (Container closure system)	stem) Vial		
Stability Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			

Time I	Period	Real time: 6 months Accelerated: 6 months			
Freque	ency	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	
Manuf	Cacturing Date	02-2022	02-2022	02-2022	
No. of	Batches		03		
	DOCUMENTS / DATA	TO BE PROVIDED	ALONG WITH STABIL	LITY STUDY DATA	
	Reference of previous approstability study data of the fi		n N/A		
r	Approval of API/ DML/C manufacturer issued by authority of country of orig	concerned regulator	Pb.2021/4570) dated 1 Drugs Administration	opy of GMP Certificate (No. 9-07-2021, issued by Food & Punjab India. The certificate s operating at satisfactory level	
	Documents for the proc approval from DRAP (in ca		n		
a	Data of stability batches attested respective docume Raw data sheets, COA, sun	nts like chromatograms			
	Compliance Record of HF audit trail reports on productions.				
ŀ	Record of Digital data log numidity monitoring of stab and accelerated)				
	rks of Evaluator:				
• Fo	llowing shall be submitted				
i	 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 				
iv	 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 (reatime and accelerated). v. Documents confirming procurement of drug substance. vi. Complete batch manufacturing record for three stability batches shall be submitted. 				
	on: Registration Board of six months.	leferred the case for s	ubmission of reply to the	he above cited shortcomings	
86.	Name, address of Appli Authorization Holder	cant / Marketing	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi		
	Name, address of Manufa	acturing site.	M/s Mission Pharmac Super Highway Karac	euticals Plot # A-94, S.I.T.E. hi	
	Status of the applicant				

 \square 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 (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 Cefuroxime1.5mg	
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 24 months.	

	Pharmaceutical Equivalence and Comparative Dissolution Profile Analytical method validation/verification of product		their product against the innovator's product Zinacef	
			1.5g manufactured by Glaxo SmithKline Firm has submitted analytical method validation study reports for drug substance as well as drug product.	
		STABILITY ST	1 -	
Manut	facturer of API	Akum Life Sciences Lin	nited	nsil Derabassi, Distt Mohali,
API L	ot No.	CFR/032/15, CFR/035/1	5, CFR/039/15	
	ption of Pack niner closure system)	Vial		
Stabili	ty Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time 1	Period	Real time: 6 months Accelerated: 6 months		
Freque	ency	Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mon		
Batch	No.	IB-031	IB-032	IB-033
Batch	Size	500 Vials	500 Vials	500 Vials
Manu	facturing Date	02-2022	02-2022	02-2022
Date o	of Initiation	15-02-2022	16-02-2022	17-02-2022
No. of	Batches		03	
87.	Name, address of Appl Authorization Holder	icant / Marketing	M/s Mission Pharmac Super Highway Karac	euticals Plot # A-94, S.I.T.E. chi
	Name, address of Manu	facturing 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 Cefuroxime750mg
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 related to nomenclature, structure, properties, solubilities, physical manufacturers, description of manufacturing and controls, specifications, analytical pand its validation, batch analysis and justing specification, reference standard, contain system and stability studies of drug substance:	
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutica development, manufacture, manufacturing process and process control, process validation protocols control of excipients, control of drug product specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials

			container closure syste	em and stability.	
	Dissolution Profile		their product against the	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Zinacef 750mg manufactured by Glaxo SmithKline	
	Analytical method v product	validation/verification		analytical method validation g substance as well as drug	
		STABILITY S	STUDY DATA		
Manufacturer of API Akum Life Sciences Lim Unit I: VIII, Sundran, Punjab-140 201 (India)		an, P.O. Mubarakrpur, Te	ehsil Derabassi, Distt Mohali,		
API L	ot No.	CFR/032/15, CFR/03	5/15, CFR/039/15		
	ption of Pack niner closure system)	Vial			
Stabili	ty Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2$			
Time l	Period	Real time: 6 months Accelerated: 6 month	s		
Freque	ency	Accelerated: 0, 3, 6 (MReal Time: 0, 3, 6 (MReal Ti	The state of the s		
Batch	No.	IB-025	IB-026	IB-027	
Batch	Size	500 Vials	500 Vials	500 Vials	
Manuf	Facturing Date	02-2022	02-2022	02-2022	
Date o	f Initiation	08-02-2022	10-02-2022	12-02-2022	
No. of	Batches		03		
88.	Name, address of Appl Authorization Holder	icant / Marketing	M/s Mission Pharma Super Highway Kara	ceuticals Plot # A-94, S.I.T.E. achi	
	Name, address of Manuf	facturing 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		
	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 ☐ Generic Drug Product		
	Dy. No. and date of subi	mission	Dy.No 20822 dated 23		
	Details of fee submitted		Rs.30,000/- dated 16-0		
	The proposed proprietar	y name / brand name	Cefuxime 250mg Injo	ection	
	Strength / concentration Pharmaceutical ingredie		Each Vial contains:		

	Cefuroxime Sodium Equivalent t Cefuroxime250mg		
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 Klin (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-template. Firm has summarized information rela to nomenclature, structure, general properti solubilities, physical form, manufacture description of manufacturing process and controspecifications, analytical procedures and validation, batch analysis and justification specification, reference standard, container closs system and stability studies of drug substance a drug product.		
Module-III Drug Substance:	Firm has submitted detailed drug substance da related to nomenclature, structure, gener properties, solubilities, physical forr manufacturers, description of manufacturing proce and controls, specifications, analytical procedure and its validation, batch analysis and justification specification, reference standard, container closur 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 batch of drug substance at both accelerated as well as re time conditions. The accelerated stability data conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for months. The real time stability data is conducted $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months.		
Module-III Drug Product:	Firm has submitted data of drug product including it description, composition, pharmaceutic development, manufacture, manufacturing proce and process control, process validation protocol control of excipients, control of drug product specifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or material container closure system and stability.		
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence their product against the innovator's product Zinac 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 substance as		

			product.	
		STABILITY S	TUDY DATA	
Man	ufacturer of API	Akum Life Sciences L Unit I: VIII, Sundra Punjab-140 201 (India	n, P.O. Mubarakrpur, Te	hsil Derabassi, Distt Mohali,
API	Lot No.	CFR/032/15, CFR/035	5/15, CFR/039/15	
	cription of Pack stainer closure system)	Vial		
Stab	ility Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$		
Time	e Period	Real time: 6 months Accelerated: 6 months		
Freq	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batc	h No.	IB-020	IB-021	IB-022
Batc	h Size	500 Vials	500 Vials	500 Vials
Man	ufacturing 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 STABIL	LITY STUDY DATA
1.	Reference of previous appr stability study data of the fi		h N/A	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		y Pb.2021/4570) dated 1 Drugs Administration	opy of GMP Certificate (No. 9-07-2021, issued by Food & Punjab India. The certificate s operating at satisfactory level
3.	Documents for the procurement of API with approval from DRAP (in case of import).		h	
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)			

- 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.

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/- date 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 t Ceftriaxone2g	
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.N 094293)	
Name and address of API manufacturer.	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpu Road, Lahore	
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-P template. Firm has summarized information related to nomenclature, structure, general properties solubilities, physical form, manufacturer description of manufacturing process and control specifications, analytical procedures and invalidation, batch analysis and justification 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	

	Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile		description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months. Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. 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 ST	CUDY DATA	
Manuf	facturer of API	Pharmagen Limited Factory: Kot Nabi Bukh	nshwala,34 K.M Ferozpu	r Road, Lahore
API L	ot No.	00421/010/2022		
	ption of Pack niner closure system)	Glass Vial		
Stabili	ity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / \text{Accelerated}$: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time l	Period	Real time: 6 months Accelerated: 6 months		
Freque	ency	Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mor		
Batch	No.	IB-091	IB-093	IB-095
Batch	Size	500 Vials	500 Vials	500 Vials
Manuf	Manufacturing Date 02-2022		02-2022	02-2022
No. of	Batches	Satches 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 (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 Ceftriaxone1g	
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months.	

			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has submitted pharmaceutical equivalence of	
	Dissolution Profile	ence and comparative		t the innovator's product
	Analytical method va product	alidation/verification of		nalytical method verification g substance as well as drug
		STABILITY ST	TUDY DATA	
Manufa	acturer of API	Pharmagen Limited Factory: Kot Nabi Bukh	shwala,34 K.M Ferozpu	r Road, Lahore
API Lo	ot No.	00421/010/2022		
	otion of Pack iner closure system)	Glass Vial		
Stabilit	y Storage Condition	Real time: 30°C ± 2°C / Accelerated: 40°C ± 2°C		
Time P	Period	Real time: 6 months Accelerated: 6 months		
Freque	ncy	Accelerated: 0, 3, 6 (Mor Real Time: 0, 3, 6 (Mor		
Batch N	No.	IB-001	IB-002	IB-003
Batch S	Size	500 Vials	500 Vials	500 Vials
Manufa	acturing Date	02-2022	02-2022	02-2022
No. of	Batches		03	
91.	Name, address of Appli Authorization Holder	cant / Marketing	M/s Mission Pharmac Super Highway Kara	euticals Plot # A-94, S.I.T.E. chi
	Name, address of Manuf	acturing 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 subn submitted	nission & Details of fee	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 Ceftriaxone1g		
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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 v	validation/verification o		alytical method verification substance as well as drug	
		STABILITY S	TUDY DATA		
Manufacturer of API Pharmagen Limited Factory: Kot Nabi Bukh			chshwala,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: $30^{\circ}C \pm 2^{\circ}C / Accelerated$: $40^{\circ}C \pm 2^{\circ}C / Accelerated$					
		Real time: 6 months Accelerated: 6 months	Real time: 6 months Accelerated: 6 months		
<u> </u>		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	f Batches		03		
92.	Name, address of App Authorization Holder	e, address of Applicant / Marketing orization 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 Ceftriaxone500mg		
	Pharmacotherapeutic Group of (API)		Cephalosporin Antibiotics		
	Pharmaceutical form of applied drug		Almost white or yellowi	Almost white or yellowish crystalline powder.	
	Reference to Finished product specifications		(USP Specification)		
	Proposed Pack size		1's		
	Proposed Pack size	<u></u>	1 S		
	Proposed Pack size Proposed unit price		As per SRO		

For generic drugs (me-to-	o status)	Rochephin 500mg Injection IV of M/s Roche Pakistan, Karachi (Reg.No. 008435)		
Name and address of AP	I manufacturer.	Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpur Road, Lahore		
Module-II (Quality Overa	all 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 Substan	ice:	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 (Conditions & duration o		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 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 Equivalent Dissolution Profile	ence and Comparative			
Analytical method validation/verification of product		Firm has submitted analytical method verification study reports for drug substance as well as drug product.		
	STABILITY ST	UDY DATA		
Manufacturer of API	Pharmagen Limited Factory: Kot Nabi Bukh	shwala,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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{RH}$		

		Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$	C / 75% ± 5%RH			
Time l	Period	Real time: 6 months Accelerated: 6 months				
Freque	ency	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		
Manut	facturing Date	02-2022	02-2022	02-2022		
No. of	Batches		03			
93.	Name, address of Applicant / Marketing Authorization Holder		M/s Mission Pharmac Super Highway Kara	eeuticals Plot # A-94, S.I.T.E. chi		
	Name, address of Manufacturing site.		M/s Mission Pharmace Super Highway Karach	euticals Plot # A-94, S.I.T.E. ni		
	Status of the applicant		✓ Manufacturer☐ Importer☐ Is involved in none	of the above (contract giver)		
	GMP status of the firm			opy of GMP certificate dated aspection conducted on 10-01-		
	Evidence of approval of	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 (☐ Generic Drug Produ			
	Dy. No. and date of submitted	nission & Details of fee	Dy.No 20846 dated 23-08-2023 Rs.30,000/- dated 16-09-2022 Certazone 500mg Injection IM			
	The proposed proprietary	name / brand name				
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each Vial contains: Ceftriaxone Sodium Equivalent to Ceftriaxone500mg			
	Pharmacotherapeutic Group of (API)		Cephalosporin Antibio	Cephalosporin Antibiotics		
	Pharmaceutical form of a	Pharmaceutical form of applied drug		vish crystalline powder.		
	Reference to Finished pr	oduct specifications	(USP Specification) 1's			
	Proposed Pack size					
	Proposed unit price		As per SRO			
	The status in reference re	egulatory authorities	USFDA Approved			
For generic drugs (me-too Name and address of API		o status)	Rochephin 500mg Injection IM of M/s Roch Pakistan, Karachi (Reg.No. 008434) Pharmagen Limited Factory: Kot Nabi Bukhshwala,34 K.M Ferozpu Road, Lahore			
		I manufacturer.				
	Module-II (Quality Over	all Summary)	template. Firm has su to nomenclature, st solubilities, physica	cturing process and controls,		

		specification, reference	alysis and justification of e standard, container closure tudies of drug substance and	
Module-III Drug Substan	ce:	related to nomenclature solubilities, physica description of manufa specifications, analy validation, batch an specification, reference	detailed drug substance data e, structure, general properties, al form, manufacturers, cturing process and controls, tical procedures and its alysis and justification of e standard, container closure idies of drug substance.	
Stability Studies of Drug (Conditions & duration o		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. Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has submitted pharmaceutical equivalence of their product against the innovator's product Rocephin 500mg IM manufactured by Roche Firm has submitted analytical method verification study reports for drug substance as well as drug product.		
Module-III Drug Product	:			
Pharmaceutical Equivalent Dissolution Profile	ence and Comparative			
Analytical method va	lidation/verification of			
	STABILITY ST	UDY DATA		
Manufacturer of API	Pharmagen Limited Factory: Kot Nabi Bukh	shwala,34 K.M Ferozpu	r Road, Lahore	
API Lot No.	00421/010/2022			
Description of Pack (Container closure system)	Glass Vial			
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency Accelerated: 0, 3, 6 (M) Real Time: 0, 3, 6 (M)				
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 Appli	cant / Marketing	M/s Mission Pharmac	euticals 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 Ceftriaxone250mg
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 (Conditions & duration o		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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 Equival Dissolution Profile	ence and Comparative	their product against the	harmaceutical equivalence of he innovator's product Inocef ctured by Barrett Hodgson d.		
	Analytical method va product	llidation/verification of		study reports for drug substance as well as drug		
		STABILITY ST	UDY DATA			
Manuf	acturer of API	Pharmagen Limited Factory: Kot Nabi Bukh	shwala,34 K.M Ferozpur Road, Lahore			
API Lo	ot No.	00421/010/2022				
	ption of Pack iner closure system)	Glass Vial				
Stabilit	ty Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$				
Time P	Period	Real time: 6 months Accelerated: 6 months				
Freque	ncy	Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mor	The state of the s			
Batch l	No.	IB-045	IB-046	IB-047		
Batch S	Size	500 Vials	500 Vials	500 Vials		
Manufa	acturing Date	02-2022	02-2022	02-2022		
No. of	Batches		03			
95.	Name, address of Appli Authorization Holder	cant / Marketing	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 Ceftriaxone250mg
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 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,

			spec anal spec	rifications, analytic ytical procedures,	s, control of drug product, cal procedures, validation of batch analysis, justification of nce standard or materials, m and stability.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile		their 250r	*		
	Analytical method v product	alidation/verification o		y reports for drug	analytical method verification g substance as well as drug	
		STABILITY S	TUDY	DATA		
Man	ufacturer of API	Pharmagen Limited Factory: Kot Nabi Buk	hshwa	la,34 K.M Ferozpu	r Road, Lahore	
API	Lot No.	00421/010/2022				
	cription of Pack ntainer closure system)	Glass Vial				
Stab	ility Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$				
Time	e Period	Real time: 6 months Accelerated: 6 months				
Freq	uency	Accelerated: 0, 3, 6 (Macelerated: 0, 3, 6 (
Batc	h No.	IB-075		IB-078	IB-080	
Batc	h Size	500 Vials		500 Vials	500 Vials	
Man	ufacturing Date	02-2022		02-2022	02-2022	
No.	of Batches			03		
	DOCUMENTS / DATA	A TO BE PROVIDED	ALON	G WITH STABII	LITY STUDY DATA	
1.	Reference of previous appr stability study data of the f		ı	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		204/2 11-20 Pakis	2022 DRAP AD/1 022 issued by Distan. The certification	opy of GMP Certificate (No. 59531263130-531) dated 22-rug Regulatory Authority of the specifies that the firm is a level of GMP compliance.	
3.	Documents for the pro- approval from DRAP (in c		Not A	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.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			-		
Rem	arks of Evaluator:					
	Section#	Observations		Firn	n's response	
<u>_</u> _	1					

3.2. S.4 • Copies of the Drug substance	
anaifications and analytical procedures	
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.	
7	
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 IV, 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			
	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		

Active Pharmaceutical ingredient (API) per unit	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 or 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 templated Summarized information related to structure, general properties Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analyst and justification of specification, reference standard, contain closure system and stability studies of drug substance and druproduct 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 drug substance, Reference standard or materials container closus system and stability studies of drug substance.
Stability studies	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 18 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months
Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceuticg Development, Manufacturing process development Microbiological attribution, Manufacturer, Master formulations Description of Manufacturing Process and Process Control 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 closurand 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 ar Analytical Method Validation Studies drug product have been submitted.

		STABILITY STUDY I	DATA				
Maı	nufacturer 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					
	cription of Pack ntainer closure system)	LDPE single-use containers					
Stat	oility Storage Condition	Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C/NMT}$ 25% RH Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ 35% RH \pm 5% RH					
Tim	ne Period	Real time: 6 months Accelerated: 6 months					
Free	quency	Accelerated: 0, 3, 6 (Mon Real Time: 0, 3, 6 (Month					
Bate	ch No.	GIS-001			GIS-002		
Bate	ch Size	5000 vials			5000 vials		
Mar	nufacturing Date	07-2023			07-2023		
No.	of Batches		02	,			
		Administrative Port	ion				
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory	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 313 th 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. Firm has submitted GMP certificate issued by Food & Drugs Administration, Maharashtra, valid till 14-04-2026.					
3.	authority of country of origin. Documents for the procurement	tt Copy of Clearance certificate attested by AD I&E DRAP, Lahore, issued					
	DRAP (in case of import).	Batch No. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare Lahore has been submitted. Comparison of M/s Horizon Healthcare has been submitted. Co					
		GLY/23002 20.00 (Grams) 22-06-2023					
		Firm has also sub- Lahore inname of			from m/s Horizon Healthca hcare taxila.	are	

4.		
5.		Compliance Record of HPLC software 21CFR & audit trail reports on product testing have been submitted.
6.	0	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 Glycopyrrolate25mcg *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 sea 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.	_

• 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.

- 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

			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 (Vo III) dated 25-10-2023 issued by Secretary CLB where "Ear/Eye Drops-II (General) section (New) has been grante Firm has also submitted panel inspection report dated 07-0 2023 wherein grant of additional section of "Ear/Eye dro 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; Tafluprost4.5 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 prostaglandianalogs.
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 templated Summarized information related to structure, general properties Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytic procedures, Validation of analytical procedure, batch analyst and justification of specification, reference standard, contain closure system and stability studies of drug substance and druproduct 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 drug substance, Reference standard or materials container closus system and stability studies of drug substance.

	Module-III (Drug Product):		Stability study conditions: Real time: $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ for 3 Accelerated: $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$ for		
			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			e have been established against the on 0.0015% (w/v) of M/s Laboratoire	
	Analytical method validation/verification of product		Analytical Method Verification Studies of Drug substance and Analytical Method Validation Studies drug product have been submitted.		
		STAI	BILITY STUDY DATA		
Man	ufacturer of API		CENTURY PHARMACEUTIALS LTD. Plant- 103, 104, 105, 106 GIDC Estate, HALOL-389350(INDIA).		
API	Lot No.	099400	09940002-TFP		
	ription of Pack tainer closure system)	LDPE single-use containers packed in a pouch.			
Stab	ility Storage Condition	Accelerated: $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \text{ RH} \pm 5\% \text{ RH}$ Real time: $5 \pm 3^{\circ}\text{C}$			
Time	e Period	Real time: 6 months Accelerated: 6 months			
Freq	uency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batc	h No.		TFP- 001	TFP- 002	
Batc	h Size		10,000	10,000	
Man	ufacturing Date		08-2023	08-2023	
No.	of Batches		0)2	
		Ad	lministrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)			e as Hydrobromide) 07-2020 and was presented in 313 th on 16-18 Nov, 2021. ve registration of	
		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.			

	1					
		 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.	by Food & Drugs Control Administration, India, valid till 10-03-2024				
3.	Documents for the procurement of API with approval from		e certificate atteste	ed by AD I&E	DRAP, Islamaba	d, has
	DRAP (in case of import).	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.					
5.	•	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 submitt humidity monitor	_		er for temperatur	e and

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.

- 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.	, , , , , , , , , , , , , , , , , , , ,	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	
	☐ 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
COMP of City City	☐ 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.

			T		
				racterization, Impurities, Control of tandard or materials container closure of drug substance.	
	Module-III (Drug Product):		Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months		
			Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months		
			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			e have been established against the olution 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.		
		STAF	BILITY STUDY DATA		
Man	ufacturer of API	Addres	uxin Long Rui Pharmaceutical CO., Ltd. ddress: Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxin ity, Liaoning Province-123000, China		
API	Lot No.	CHR00	07-20230118-D01-M04-01		
	ription of Pack tainer closure system)	LDPE s	single-use containers packed	in a pouch.	
Stab	ility Storage Condition		me: 30°C ± 2°C/35% RH ± 5 rated: 40°C ± 2°C/NMT 25%		
Time	e Period		ne: 6 months rated: 6 months		
Freq	uency		ccelerated: 0, 3, 6 (Months) eal Time: 0, 3, 6(Months)		
Batc	h No.		LFT-001	LFT-002	
Batc	h Size		10,000	10,000	
Man	ufacturing Date		07-2023	07-2023	
	of Initiation		31-07-2023	31-07-2023	
No.	of Batches		(02	
			ministrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)				

		 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.	* *	Firm had provided DML no. LIAO 20150233 valid upto: 17-01-2027 issued by Liaoning Medical Products Administration				
3.	Documents for the procurement of API with approval from	Copy of Clearance certificate attested by AD I&E DRAP, Islamabad, has				
	DRAP (in case of import).	Batch No.	Invoice No.,	Quantity Imported	Date of approval by DRAP	
		CHR007- 20230118- D01-M04-01	HOR4205240	0.50 (Kilogram s)	20-Jul-2023	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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 have been submitted.				
6.		Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.				

Remarks of Evaluator II:

(real time and accelerated)

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 	• Firm has submitted 6 th month
	performing test of "sodium thiosulfate assay" during stability studies.	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.

- 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.

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	Firm has submitted stability study data of 3 batches	
storage conditions	The accelerated stability study data is conducted at	
	$40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real	
	time stability study data is conducted at 30°C ±2°C /	
	$75\% \pm 5\%$ 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		
	GMP status of the firm	Firm has been granted new license dated 7 th 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 7 th 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-PI 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 closur system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed data for both drugsubstance 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 drugsubstance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batche of drug substance at both accelerated as well as reatime conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 36 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols control of excipients, control of drug product specifications, analytical procedures, 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.

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. 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) Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 and valid for 02 years Firm has submitted copy of commercial invoic specifying purchase of 2Kg tamsulosin pellets date 10-06-2023. Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets. COA and summary data their HPLC system is not 2 CFR compliant. Firm has submitted that their HPLC system is not 2 CFR compliant.		Analytical method validation/verification of product			analytical method for	the drug substance. report of verification of
Islamabad. API Lot No. TMS415 Description of Pack (Container closure system) Stability Storage Condition Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Time Period Real time: 6 months Accelerated: 6 months Accelerated: 6 months Real Time: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) Batch No. T001 T002 T003 Batch Size 1000 Capsule 1000 Capsule 1000 Capsule 1000 Capsule Manufacturing Date 07-2023 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) 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. 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) Approval of API with part of temperature and humidity monitoring of real time an accelerated stability chambers.			STABILITY	ST	UDY DATA	
Description of Pack (Container closure system) Alu-Alu Blister	Mar	nufacturer of API		euti	icals Plot No. 22-23, Inc	dustrial Triangle Kahuta Road
Stability Storage Condition Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	API	Lot No.	TMS415			
Accelerated: 40°C ± 2°C / 75% ± 5%RH Time Period Real time: 6 months			Alu-Alu Blister			
Accelerated: 6 months Frequency Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) Batch No. Batch No. Batch Size 1000 Capsule	Stab	bility Storage Condition				
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) 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. 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 stability chambers (real time and accelerated stability chambers.	Tim	e Period		ıs		
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) 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. 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) 1000 Capsule 1000	Free	luency	The state of the s			
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 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. 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) O7-2023 12-07-2023 13-07-2023 13-07-2023 Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 and valid for 02 years submitted copy of commercial invoic specifying purchase of 2Kg tamsulosin pellets date 10-06-2023. Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets. COA and summary data sheets. Firm has submitted that their HPLC system is not 2 CFR compliant. Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	Bato	ch No.	T001		T002	T003
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 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. 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) 11-07-2023 12-07-2023 13-07-2023 13-07-2023 13-07-2023 No. of Batches Oga New License Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 and valid for 02 years Firm has submitted copy of commercial invoic specifying purchase of 2Kg tamsulosin pellets date 10-06-2023. Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets. COA and summary data sheets. Firm has submitted that their HPLC system is not 2 CFR compliant. Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	Bato	ch Size	1000 Capsule		1000 Capsule	1000 Capsule
DOCUMENTS / DATA 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. 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) DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA New License Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 and valid for 02 years specifying purchase of 2Kg tamsulosin pellets date 10-06-2023. Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets. COA and summary data sheets. Firm has submitted that their HPLC system is not 2 CFR compliant. 6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Mar	nufacturing Date	07-2023		07-2023	07-2023
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. 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) Poet Map Certificate on the basis of evaluation conducted on 14-06-2022 and valid for 02 years Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 and valid for 02 years Firm has submitted copy of commercial invoic specifying purchase of 2Kg tamsulosin pellets date 10-06-2023. Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets. COA and summary data sheets. Firm has submitted that their HPLC system is not 2 CFR compliant. Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	Date	e of Initiation	11-07-2023		12-07-2023	13-07-2023
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. 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) New License Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 and valid for 02 years Firm has submitted copy of commercial invoic specifying purchase of 2Kg tamsulosin pellets date 10-06-2023. Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets. COA and summary data sheets. Firm has submitted that their HPLC system is not 2 CFR compliant. Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	No.	of Batches			03	
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. 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) Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 and valid for 02 years Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 and valid for 02 years Firm has submitted copy of commercial invoic specifying purchase of 2Kg tamsulosin pellets date 10-06-2023. Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets. COA and summary data their HPLC system is not 2 CFR compliant. Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		DOCUMENTS / DATA	A TO BE PROVIDED) A	LONG WITH STABI	LITY STUDY DATA
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 Documents for the procurement of API with approval from DRAP (in case of import). Firm has submitted copy of commercial invoic specifying purchase of 2Kg tamsulosin pellets dated 10-06-2023. Data of stability batches will be 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) Firm has submitted that their HPLC system is not 2 CFR compliant. Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	1.			New License		
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) specifying purchase of 2Kg tamsulosin pellets dated 10-06-2023. Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets. Firm has submitted that their HPLC system is not 2 CFR compliant. Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	2.	manufacturer issued by concerned regulatory			Copy of GMP Certific	
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) batches along with chromatograms, raw data sheets, COA and summary data sheets. Firm has submitted that their HPLC system is not 2 CFR compliant. Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	3.			specifying purchase of 2Kg tamsulosin pellets dated		
audit trail reports on product testing CFR compliant. 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.	4.	attested respective documents like chromatograms,		batches along with chr	omatograms, raw data sheets,	
humidity monitoring of stability chambers (real temperature and humidity monitoring of real time and accelerated) temperature and humidity monitoring of real time and accelerated stability chambers.	5.	•			tt their HPLC system is not 21	
Evaluation by PEC:	6.	humidity monitoring of stability chambers (real		temperature and humid	lity monitoring of real time and	
	Evaluation by PEC:					

- 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.

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 Cefoperazone250mg Sulbactam Sodium Eq. to Sulbactam250mg
	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 proces and controls, impurities, specifications, analytica procedures and its validation, batch analysis and justification of specification, reference standard container closure system and stability studies of drug substance.
	Stability Studies of Dr (Conditions & duration		Firm has submitted stability study data of 3 batche of drug substance as per Zone IV-A conditions.
			Firm has submitted data of drug product including it description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols control of excipients, control of drug product specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials container closure system and stability.
	Pharmaceutical Equiv Dissolution Profile	valence and Comparat	Firm has submitted results of pharmaceutical equivalence for their product against 2sum injection of Healthtek
	Analytical method product	validation/verification	of Firm has submitted report of verification studies of analytical method for the drug substance and product.
	,	STABILITY	STUDY DATA
Manu			armaceutical Group Hengxin Pharmaceutical Co Ltd Wes Economic Development Zone Feixian China
API L	ot No.	11C0312207001	
	ription of Pack ainer closure system)	Glass Vials	
Stabil	ity Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$	
Time	Period	Real time: 6 months Accelerated: 6 month	ıs
Frequ	ency	Accelerated: 0, 1, 2, 3 Real Time: 0, 3, 6 (M	
Batch	No.	C020DS01	C020DS02
Batch	Size	2000 vials	2000 vials
Manu	facturing Date	09-2022	09-2022
Date of Initiation 17-10-2		17-10-2022	17-10-2022
No. of Batches			03
1	DOCUMENTS / DATA 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.		
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.	attested respective documents like chromatograms,	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
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

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	This is to bring to your kind information that we are
	facility i.e. Dry Powder Vial Injection	using ready to fill cefoperazone sodium and
	(Cephalosporin) section was granted by	sulbactam sodium for filling in vials and no
	Licensing Division DRAP on 27-02-2023,	excipient is used in the formulation of said product.
	and the inspection by the panel was carried	The filling of bulk API has been performed in our
	out on 16-11-2022. You have manufactured	R&D section under under Laminar Flow Hood with
	the batches in September 2022, before the	HEPA filter in aseptic conditions.
	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.	
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.	

- 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 Cefoperazone500mg Sulbactam Sodium Eq. to Sulbactam500mg
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	Firm has submitted stability study data of 3 batches
(Conditions & duration of Stability studies)	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 Equivolence Dissolution Profile	alence and Compara	tive		Firm has submitted results of pharmaceutical equivalence for their product against 2sum injection of Healthtek	
	Analytical method v product	validation/verification	of		d report of verification studies of I for the drug substance and	
		STABILITY	ST	UDY DATA		
Manufa	cturer of API				ngxin Pharmaceutical Co Ltd West nt Zone Feixian China	
API Lot	t No.	11C0312207001				
	ntion of Pack ner closure system)	Glass Vials				
Stability	y Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm$				
Time Pe	eriod	Real time: 6 months Accelerated: 6 month	hs			
Frequer	ncy	Accelerated: 0, 1, 2, Real Time: 0, 3, 6 (N				
Batch N	lo.	C021DS01		C021DS02		
Batch S	ize	2000 vials		2000 vials		
Manufa	cturing Date	09-2022		09-2022		
Date of	Initiation	17-10-2022		17-10-2022		
No. of I	Batches			03		
	DOCUMENTS / DATA	A TO BE PROVIDE	D A	LONG WITH STA	ABILITY STUDY DATA	
	Reference of previous with stability study data of		ions	NA		
n	Approval of API/ DML nanufacturer issued buthority of country of or	y concerned regular			l copy of DML of the firm issued alid till 26-10-2025.	
	Documents for the procurement of API with approval from DRAP (in case of import).		with	specifying import Sulbactam sodium	ed copy of License to Import of 20Kg Cefoperazone sodium- dated 18-08-2022. Firm has also Goods Declaration dated 10-08-	
a	Data of stability batches will be supported by attested respective documents like chromatograms. Raw data sheets, COA, summary data sheets etc.		ıms,			
5. C	Compliance Record of Fundit trail reports on production	IPLC software 21CFI		*		
6. R						
Evaluat	tion 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	This is to bring to your kind information that we are
	facility i.e. Dry Powder Vial Injection	using ready to fill cefoperazone sodium and
	(Cephalosporin) section was granted by	sulbactam sodium for filling in vials and no
	Licensing Division DRAP on 27-02-2023,	excipient is used in the formulation of said product.
	and the inspection by the panel was carried	The filling of bulk API has been performed in our
	out on 16-11-2022. You have manufactured	R&D section under under Laminar Flow Hood with
	the batches in September 2022, before the	HEPA filter in aseptic conditions.
	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.	
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.	

- 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	

2GET IV/IM 2g Powder for Injection
Each Vial Contains: Cefoperazone Sodium Eq. to Cefoperazone1g Sulbactam Sodium Eq. to Sulbactam1g
Sterile white to almost white powder filled in transparent glass vials
Cephalosporin antibiotic
Innovator's specs
1's
800
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
2Sum injection by Sami
Shandong Luoxin Pharmaceutical Group Hengxir Pharmaceutical Co Ltd West Side of Yanbin Road Economic Development Zone Feixian China
Firm has submitted QOS as per WHO QOS-PE 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.
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.
Firm has submitted stability study data of 3 batche of drug substance as per Zone IV-A conditions.
Firm has submitted data of drug product including it description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols control of excipients, control of drug product specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials

			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	ST	UDY DATA	
Manu	facturer of API				ngxin Pharmaceutical Co Ltd West nt Zone Feixian China
API L	Lot No.	11C0312207001			
	iption of Pack ainer closure system)	Glass Vials			
Stabil	ity Storage Condition	Real time : $30^{\circ}C \pm 2$ Accelerated: $40^{\circ}C \pm 2$			
Time	Period	Real time: 6 months Accelerated: 6 mont	hs		
Frequ	ency	Accelerated: 0, 1, 2, Real Time: 0, 3, 6 (N			
Batch	No.	C022DS01		C022DS02	
Batch	Size	2000 vials		2000 vials	
Manu	facturing Date	09-2022		09-2022	
Date of	of Initiation	17-10-2022		17-10-2022	
No. of	f Batches			03	
	DOCUMENTS / DATA	A TO BE PROVIDE	D A	LONG WITH STA	ABILITY STUDY DATA
1.	Reference of previous with stability study data		ions	NA	
2.	Approval of API/ DML manufacturer issued by authority of country of or	y concerned regula		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.	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 F audit trail reports on proc		R &	Submitted	
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)				
Evalu	ation by PEC:				

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 F	Response by the firm	
	1.	The approval of the requisite manufacturing T	This is to bring to your kind information that we are	
l		facility i.e. Dry Powder Vial Injection u	using ready to fill cefoperazone sodium and	

2.	(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. 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	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.
	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 chloride0.6g Calcium Chloride dihydrate0.02g Potassium Chloride0.3g Sodium lactate0.31g Dextrose anydrous5g
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 Substar	nce:	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	
Stability Studies of Drug (Conditions & duration of		system and stability studies of drug substance. Firm has submitted stability study data for all drug substances	
Module-III Drug Produc	•	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
Pharmaceutical Equival Dissolution Profile	lence and Comparative	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 vaproduct	alidation/verification of	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 ST	TUDY DATA	
Economic Development Calcium chloride M/s Hebei Huachen Development Zone, Heb Potassium chloride CFL CLFCHEMISCH KÖTHENWALDSTR. 2 Sodium lactate Wuhan Sanjing Space G Dextrose: Weifang She		Pharmaceutical Co. Ltd. Huanghua Economic ei PR China. HE FABRIK LEHRTE GMBH & CO.KG e- 6 - 31275 LEHRTE GERMANY ood Biotech Co Ltd Hebei Province China ngtai Medicine Co., Ltd. The east of Changda Road, ag city, Shandong province, P.R.China 03 25 22000506	
Description of Pack	Dextrose: XW20220913	3	
(Container closure system)	Polypropylene		
Stability Storage Condition Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$		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	ı No.	Trial # 1	Trial # 2	Trial # 3	
Batch	Size	100 Bottles	100 Bottles	100 Bottles	
Manu	facturing Date	04-2023	04-2023	04-2023	
Date of	of Initiation	10-04-2023	11-04-2023	12-04-2023	
No. of	f Batches		03		
	DOCUMENTS / DATA	TO BE PROVIDED A	ALONG WITH STABII	LITY STUDY DATA	
	Reference of previous apprestability study data of the fi		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.					
	Documents for the proc approval from DRAP (in ca		cith 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 clearance certificate dated 02-03-2023. The invoideclare purchase of 1000Kg calcium chloride. Potassium chloride: Firm has submitted copy clearance certificate dated 17-11-2022. The invoideclare 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		
	Data of stability batches will be supported by attested respective documents like chromatograms Raw data sheets, COA, summary data sheets etc.		•		
	Compliance Record of HF audit trail reports on produc		k NA		
6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)					
	nation by PEC:				
Sr. N	No Shortcomings comm	unicated	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

- 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 chloride0.6g Calcium Chloride dihydrate0.02g Potassium Chloride0.3g Sodium lactate0.31g Dextrose anydrous5g
	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, pharmaceutica development, manufacture, manufacturing process and process control, process validation protocols control of excipients, control of drug product specifications, analytical procedures, validation or analytical procedures, batch analysis, justification or specifications, reference standard or materials container closure system and stability.	
	Tonium of the same system and swelling.	

	Dissolution Profile			quality tests for their product ator product 'Sterifluid-RLD Pharma."	
Analytical method validation/verification of product					
		STABILITY ST	TUDY 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			
		Sodium Chloride: 220903 Calcium chloride: 221225 Potassium chloride: 3422000506 Sodium lactate: 22RS12234 Dextrose: XW20220913			
Description of Pack (Container closure system)		Polypropylene			
		Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
		Real time: 6 months Accelerated: 6 months			
Frequ	nency	Accelerated: 0, 1, 2, 3, 6 Real Time: 0, 3, 6 (Mon	` /		
Batch	n No.	Trial # 4	Trial # 5	Trial # 6	
Batch	n Size	100 Bottles	100 Bottles	100 Bottles	
Manı	ıfacturing Date	04-2023	04-2023	04-2023	
-	of Initiation	10-04-2023	11-04-2023	12-04-2023	
No. o	of Batches		03		
	DOCUMENTS / DATA	A TO BE PROVIDED A	LONG WITH STABII	LITY STUDY DATA	
1.	Reference of previous approval of applications with stability study data of the firm (if any)		is a newly established license.		
2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.					

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

- 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 Dr Manufacturing License (DML No. 000947) dated 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 anhydrous25g	
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	

	Pharmacoutical Equiva	Janca and Comparativ	process control, procedures, control analytical procedure procedures, batch specifications, refer container closure syst	ence standard or materials, em and stability.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile		equivalence for the against the compara	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 v product	alidation/verification o	method for the drug s Firm has submitted re	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		
Manı	ufacturer of API	0 0	edicine Co., Ltd The ear Shandong province, P.R	ast of Changda Road, Changle .China.	
API I	Lot No.	XW20220913			
	ription of Pack tainer closure system)	Polypropylene			
Stabi	lity Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequency Accelerated: 0, 1, 2, 3, 6 Real Time: 0, 3, 6 (Mor					
Batch	n No.	T010	T011	T012	
Batch	n Size	100 Bottles	100 Bottles	100 Bottles	
Manu	ufacturing Date	01-2023	01-2023	01-2023	
Date	of Initiation	10-01-2023	11-01-2023	12-01-2023	
No. c	of Batches		03		
	DOCUMENTS / DAT	A TO BE PROVIDED	ALONG WITH STAB	ILITY STUDY DATA	
1.	Reference of previous app stability study data of the	* *	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 & NA audit trail reports on product testing				
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)				

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

- 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.

7.	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 chloride0.45g Dextrose anydrous5g	
	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 1/2 INFUSION by Otsuka	

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, manufacturents, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, analytical process and controls, impurities, specifications, analytical process and controls, impurities, specifications, analytical proceedings of the process and controls, impurities, specifications, analytical proceedings and its validation, batch analysis and justification of specification, sandytical procedures and 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: 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, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile Pharmaceutical Equivalence and Comparative Dinsolution Profile Pharmac			Ta	
template, Firm has summarized information related to nomenclature, 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: 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 stability study data for all drug substances and drug product: Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process; control of excipients, control of drug product, specifications, analytical procedures, validation protocols, control of excipients, control of drug product, specification of specifications, reference standard or materials, container closure system and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile Analytical method validation/verification of product procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability studies of the quality tests for their product against the comparator product "Mascol DS ½ Infusion manufactured by Searle Pakistan Ltd." Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification	rvame and address of API manufacturer.		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,	
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, before a system and stability studies of drug substance. Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Firm has submitted stability study data for all drug substances Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile Dissolution Profile	Module-II (Quality Over	all Summary)	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	
Conditions & duration of Stability studies Substances	Module-III Drug Substan	nce:	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.	
description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 Analytical method validation/verification of 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			Firm has submitted stability study data for all drug substances	
Dissolution Profile Polypropylene Polyproduct Polypropylene Polypropy		<u> </u>	development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials,	
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		ence and Comparative	equivalence for the quality tests for their product against the comparator product "Macsol DS ½	
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		nlidation/verification of	method for the drug substance. Firm has submitted report of verification of analytical	
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 ST		TUDY DATA	
Description of Pack (Container closure system) Polypropylene	Manufacturer of API	Economic Development Dextrose: Weifang She	Zone, Hebei PR China. engtai Medicine Co., Ltd The east of Changda Road,	
(Container closure system)	API Lot No.			
Stability Storage Condition Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$	Description of Pack (Container closure system)	Polypropylene		
	Stability Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ /	65% ± 5%RH	

		Accelerated: $40^{\circ}\text{C} \pm 2$	2°C / 75% ± 5%RH		
Time l	Period	Real time: 6 months Accelerated: 6 months			
Freque	equency 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	
Manuf	facturing Date	01-2023	01-2023	01-2023	
Date o	of Initiation	14-01-2023	15-01-2023	16-01-2023	
No. of	f Batches		03		
	DOCUMENTS / DATA	A TO BE PROVIDE	ALONG WITH STAB	ILITY STUDY DATA	
	Reference of previous appr stability study data of the f		th Not applicable since it	is a newly established license.	
1			ry Manufacturing License NMPA China valid till Dextrose: Firm has su	NMPA China valid till 11-08-2025. Dextrose: Firm has submitted copy of Manufacturing license (No. Lu20200513) issued by NMPA China	
	B. Documents for the procurement of API with approval from DRAP (in case of import).		clearance certificate da declare purchase of 25 Dextrose: Firm has certificate dated 31-	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.	
8	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.				
1	5. Compliance Record of HPLC software 21CFR & NA audit trail reports on product testing		& NA		
1			al temperature and humi	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	
Evalu	ation by PEC:				
G N	T CIL 4	• 4 1	D 1 (1 6)		
1.	Sr. No Shortcomings communicated Response by the firm 1. Submit water loss studies conducted during stability since your container closure system is semi-permeable.				
• N p r • N	 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. 				
100.	Name, address of Appli Authorization Holder	cam / warketing		armaceuticals (Pvt) Ltd. Plot , Industrial Estate, Gadoon lbi.	
	Name, address of Manufacturing site.			maceuticals (Pvt) Ltd. Plot No. Istrial 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 Drumanufacturing License (DML No. 000947) dated 1 11-2021.	
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Dru 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 chloride0.45g Dextrose anydrous5g	
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 1/2 INFUSION by Otsuka	
Name and address of API manufacturer.	Sodium Chloride: M/s Hebei Huach Pharmaceutical Co. Ltd. Huanghua Econom Development Zone, Hebei PR China. Dextrose: Weifang Shengtai Medicine Co., Ltd T east of Changda Road, Changle County, Weifang ci Shandong province, P.R.China.	
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-Fitemplate. Firm has summarized information related 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 a stability studies of drug substance and drug product.	
Module-III Drug Substance:	Firm has submitted detailed data for drug substan	

		description of manufacturing impurities, specification validation, batch a specification, referen	s, physical form, manufacturers, facturing process and controls, ons, analytical procedures and its malysis and justification of ce standard, container closure rudies of drug substance.	
Stability Studies of Dru (Conditions & duration		Firm has submitted s substances	stability study data for all drug	
Module-III Drug Product: I C C C C C C C C C C C C C C C C C C		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
Pharmaceutical Equiv 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 ST	TUDY DATA		
Economic Development Dextrose: Weifang Sho		Zone, Hebei PR China	td The east of Changda Road,	
API Lot No.	Sodium Chloride: 2209 Dextrose: XW20220913			
Description of Pack (Container closure system)	Polypropylene			
Stability Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Time Period Real time: 6 months Accelerated: 6 months				
Frequency Accelerated: 0, 1, 2, 3, 6 Real Time: 0, 3, 6 (Mor				
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 / DA	TA TO BE PROVIDED A	LONG WITH STAB	ILITY STUDY DATA	
1. Reference of previous ap stability study data of the		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.	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.
Eval	uation 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

- 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
	Each 100ml contains:
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sodium chloride0.86g Calcium Chloride dihydrate0.033g Potassium Chloride0.03g
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

			process control, proc of excipients, control analytical procedur procedures, batch	analysis, justification of ence standard or materials,	
Pharmaceutical Equivalence and Comparate Dissolution Profile Analytical method validation/verification product		alence and Comparati	equivalence for the	d results of pharmaceutical quality tests for their product or product "Macrin RS Infusion cle Pakistan Ltd."	
		ralidation/verification	method for the drug s Firm has submitted re	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		
		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 l	Lot No.	Sodium Chloride: 220903 Calcium chloride: 221225 Potassium chloride: 3422000506			
	ription of Pack tainer closure system)	Polypropylene			
Stabi	lity Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	uency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batcl	n No.	T016	T017	T018	
Batcl	n Size	100 Bottles	100 Bottles	100 Bottles	
Manu	ufacturing Date	04-2023	04-2023	04-2023	
Date	of Initiation	10-04-2023	11-04-2023	12-04-2023	
No. o	of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		ILITY STUDY DATA			
1.	Reference of previous app stability study data of the	* *	ith Not applicable since it	is a newly established license.	
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Manufacturing Licens NMPA China valid til Calcium chloride: Manufacturing Licens	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.	

	T	T
		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.	· ·
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and	Firm has submitted record of digital data logger for
	humidity monitoring of stability chambers (real time and accelerated)	
Eval	uation by PEC:	-
Sr.	No Shortcomings communicated	Response by the firm
1.	Submit water loss studies conducted during	
		·
	stability since your container closure system is	\$ I

- 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: Acetylcysteine200mg
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 Pa Gedian Economy Development Zone, E' Zhou Cit Hubei China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-F template. Firm has summarized information relat to nomenclature, structure, general properties solubilities, physical form, manufactured description of manufacturing process and control impurities, specifications, analytical procedures at its validation, batch analysis and justification specification, reference standard, container closury system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed data for drug substandata related to nomenclature, structure, generoperties, solubilities, physical formanufacturers, description of manufacturing proceand controls, impurities, specifications, analytic procedures and its validation, batch analysis at justification of specification, reference standar 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 batch of drug substance.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutic development, manufacture, manufacturing process and process control, process validation protocol control of excipients, control of drug product specifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or material container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutic equivalence for their product against Mucolat Sachet of Abbott

			Firm has submitted results of CDP for their product against Mucolator Sachet of Abbott		
	Analytical method v product	validation/verification o		erification studies of the drug ical method validation of the	
		STABILITY S	TUDY DATA		
Man	ufacturer of API	Wuhan Grand Hoyo Co Ltd. No 1, Industrial Park Gedian Economy Development Zone, E' Zhou City, Hubei China			
API	Lot No.	S202202004			
	ription of Pack tainer closure system)	Aluminium foil Sachet	į		
Stabi	llity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time	e Period	Real time: 6 months Accelerated: 6 months			
Freq	uency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batc	h No.	T001	T002	T003	
Batc	h Size	500 Sachet	500 Sachet	500 Sachet	
Man	ufacturing 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	A TO BE PROVIDED A	ALONG WITH STABI	LITY STUDY DATA	
1.	Reference of previous app stability study data of the		Not submitted by the f	irm	
2.	* *	y concerned regulator		opy of GMP certificate (No, by CFDA China valid till 03-	
3.	Documents for the procurement of API with approval from DRAP (in case of import).			g 0.6Kg Acetylcysteine. Firm	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			cord of testing of stability	
5.	Compliance Record of H audit trail reports on produ		Firm has submitted co	ompliance certificate of HPLc	
6.	Record of Digital data lo humidity monitoring of time and accelerated)			cord of digital data logger for lity monitoring of real time and nambers.	
Eval	uation by PEC:		· · · · · · · · · · · · · · · · · · ·		

Evaluation by PEC:

- 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.

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: Empagliflozin10mg
	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

		and controls, impurit procedures and its v justification of speci	lities, physical form, otion of manufacturing process ies, specifications, analytical alidation, batch analysis and affication, reference standard, em and stability studies of drug	
Stability Studies of Drug Substance (Conditions & duration of Stability studies)		of drug substance at b time conditions. The conducted at 40°C ±	ability study data of 3 batches oth accelerated as well as real accelerated stability data is 2°C / 75% ± 5% RH for 6 estability data is conducted at RH for 24 months.	
Module-III Drug Pro	oduct:	its description, codevelopment, manufa and process control, control of excipients specifications, analyti analytical procedures,	ata of drug product including omposition, pharmaceutical acture, manufacturing process process validation protocols, s, control of drug product, acal procedures, validation of batch analysis, justification of ence standard or materials, em and stability.	
Pharmaceutical Equ Dissolution Profile	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 product	validation/verification of		erification studies of the drug ical method validation of the	
	STABILITY ST			
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	L-E-20211130-D06-E06-02		
Description of Pack (Container closure system)	Alu-alu blister pack	Alu-alu blister pack		
Stability Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	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 / DA	ATA TO BE PROVIDED A	LONG WITH STABI	LITY STUDY DATA	
1. Reference of previous stability study data of t	approval of applications with he firm (if any)	Not submitted by the fi	irm	

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.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Eval	uation 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: Empagliflozin12.5mg Metformin HCl1000mg	

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 4 th 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 v	alidation/verification		rerification studies of the drug ical method validation of the	
	STUDY DATA			
Avenue Zhejiang Toume Taizhou Zhejiang China		oumengang Economic De ina rugs Limited Plot No 211-2	gs Limited Plot No 211-213 Road No 2, GIDC Sarigam	
API Lot No.	Empagliflozin: EPG Metformin: MEF/11			
Description of Pack (Container closure system)	Alu-alu blister pack			
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time Period	Real time: 6 months Accelerated: 6 month	ns		
Frequency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (M			
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	A TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA	
1. Reference of previous app stability study data of the	* *	ith Not submitted by the f	Not submitted by the firm	
manufacturer issued by	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory		the firm issued by CFDA China	
	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.	
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		ns, batches along with rav	batches along with raw data sheets, COA and	
5. Compliance Record of H audit trail reports on produ		& Firm has submitted consystem	-	
	humidity monitoring of stability chambers (real		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: Empagliflozin5mg Metformin HCl500mg	
	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 4 th 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 Over	rall 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 Substa	nce:	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 (Conditions & duration of	•	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 Produc	t:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
Pharmaceutical Equiva Dissolution Profile	lence and Comparative	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 ST		UDY DATA	
Manufacturer of API	Avenue Zhejiang Toum Taizhou Zhejiang China	s Limited Plot No 211-213 Road No 2, GIDC Sarigam	
API Lot No. Empagliflozin: EPG2 Metformin: MEF/11			
Description of Pack (Container closure system) Alu-alu blister pa			
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$		

		Accelerated: 40°C ± 2°	C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months			
Freq	uency	Accelerated: 0, 3, 6 (Meal Time: 0, 3, 6 (Meal			
Batc	h No.	KE-23-001	KE-23-002	KE-23-003	
Batc	h Size	5000 Tablet	5000 Tablet	5000 Tablet	
Man	ufacturing Date	01-2023	01-2023	01-2023	
Date	of Initiation	14-01-2023	14-01-2023	14-01-2023	
No. o	of Batches		03		
	DOCUMENTS / DATA	TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA	
1.	Reference of previous appr stability study data of the f		h Not submitted by the f	irm	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		the firm issued by CFI Metformin: Firm ha	OA China as submitted copy of GMP Good & Drugs Administration	
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.			batches along with raw data sheets, COA and summary data sheets.	
5.	Compliance Record of HI audit trail reports on produ		Firm has submitted co system	ompliance certificate of HPLc	
6.			Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Eval	uation by PEC:				
 Decision: Approved with Innovator's specifications. Manufacturer will place first three production batches on long term stability studies throug proposed shelf life and on accelerated studies for six months as per the commitment submitted 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. 			ne commitment submitted in as per the commitment		
114.	Name, address of Appli Authorization Holder	icant / Marketing	M/s Don Valley Pha Km, Ferozepur Road	armaceuticals (Pvt) Ltd 31- l, Lahore.	
	Name, address of Manuf	acturing site.	M/s Don Valley Phar Ferozepur Road, Laho	maceuticals (Pvt) Ltd 31-Km, ore.	
	Status of the applicant		☑ Manufacturer☐ Importer		

	\square 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 (Generally 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: Empagliflozin5mg Metformin HCl1000mg		
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 4 th 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.		
	(Conditions & duration of Stability studies) Module-III Drug Product: I i i i i i i i i i i i i i i i i i i		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 Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. 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		
M					
	Analytical method validation/verification of product		Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.		
		STABILITY ST	UDY DATA		
Manufact	urer of API	Empagliflozin: Zhejiang Hongyuan Pharmaceutical Co Ltd No 6 Donghai 4 th 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 N	Vo.	Empagliflozin: EPG22 Metformin: MEF/1112			
	on of Pack r closure system)	Alu-alu blister pack			
Stability S	Storage Condition		ne: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ ated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Period Real time: 6 months Accelerated: 6 months					
Frequency Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mont					
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 Ba	No. of Batches		03		
De	DOCUMENTS / DATA TO BE PROVIDED A		LONG WITH STABII	LITY STUDY DATA	
	erence of previous app ility study data of the	roval of applications with firm (if any)	Not submitted by the fi	irm	

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.	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.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted compliance certificate of HPLc system	
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	
Evalu	uation 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	Each capsule contains: Dexlansoprazole (as dual delayed release pellets)60mg	
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		
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 batche 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 Firm has submitted verification studies of the drug					
	product substance and the drug product.					
			STABILITY	YST	UDY DATA	
Manufacturer of API M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle Kallslamabad.				dustrial Triangle Kahuta Road		
API	Lot N	0.	DLP954			
		n of Pack closure system)	Alu-alu blister			
Stab	ility S	torage Condition	Real time : 30°C ± 2 Accelerated: 40°C ±			
Tim	e Perio	od	Real time: 6 month Accelerated: 6 mon			
Freq	luency		Accelerated: 0, 3, 6 Real Time: 0, 3, 6 (•		
Batc	h No.		DDT004		DDT005	DDT006
Bato	h Size	:	1000 Capsule		1000 Capsule	1000 Capsule
Man	ufactu	ring Date	06-2023		06-2023	06-2023
Date	of Ini	tiation	14-06-2023		15-06-2023	16-06-2023
No.	No. of Batches 03					
	DC	OCUMENTS / DATA	TO BE PROVIDE	D A	LONG WITH STABI	LITY STUDY DATA
1.		rence of previous appr lity study data of the f		with	New License	
2.	manı		concerned regula		Firm has submitted co on the basis of inspect	opy of GMP certificate issued ion 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 date 06-04-2023 specifying purchase of 50K dexlansoprazole pellets 22.5% by Seraph pharma			ing purchase of 50Kg		
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 & The firm submitted that their HPLC system is not 21 audit trail reports on product testing CFR compliant therefore the audit trail reports are not applicable.					
6.	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.					
Eval	luation	n by PEC³:				
Sr. No Shortcoming Response by the firm			f loon latter			
1.		Submit loan letter fr because the submitte invoice is for Seraph	ed commercial	Fir	m has submitted copy o	i ioan letter
1	invoice is for Scraph pharma					

• 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 Substa	nce:	data related to nom properties, solubi manufacturers, descrip and controls, impurit procedures and its v justification of speci	etailed data for drug substance nenclature, structure, general dities, physical form, ption of manufacturing process ties, specifications, analytical alidation, batch analysis and diffication, reference standard, em and stability studies of drug	
	(Conditions & duration of Stability studies) Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile		ability study data of 3 batches	
Module-III Drug Produc			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
			I results of pharmaceutical e quality tests for their product et of Seraph Pharma. esults of CDP for their product et of Seraph Pharma.	
Analytical method v product	alidation/verification of		erification studies of the drug ical method validation of the	
•	STABILITY ST	UDY 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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0, 3, 6 (Mor Real Time: 0, 3, 6 (Mor	· · · · · · · · · · · · · · · · · · ·		
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	A TO BE PROVIDED A	LONG WITH STABI	LITY STUDY DATA	
1. Reference of previous approximately stability study data of the		New License		

2.	**	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.	
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.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Eval	uation 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.	
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.	
4.	Submit loan letter from Seraph pharma because the submitted commercial invoice is for Seraph pharma.	Firm has submitted copy of loan 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.

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	
	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

			control of excipient specifications, analytical procedures, specifications, refere container closure syst	·
	Pharmaceutical Equiva Dissolution Profile	llence and Comparativ	equivalence for all the against Vonocel Table	sults of CDP for their product
	Analytical method v product	alidation/verification of		erification studies of the drug ical method validation of the
		STABILITY S	TUDY DATA	
Manu	ifacturer of API	Jiangxi Synergy Phar Fengxin, Jiangxi Provi		ngxi Fengxin Industrial Park,
API I	Lot No.	104-20220707BD		
	ription of Pack tainer closure system)	Alu-alu blister pack		
Stabi	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequ	iency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch	ı No.	VGT004	VGT005	VGT006
Batch	n Size	1000 Tablet	1000 Tablet	1000 Tablet
Manı	ıfacturing Date	06-2023	06-2023	06-2023
Date	of Initiation	26-06-2023	26-06-2023	26-06-2023
No. c	of Batches		03	
	DOCUMENTS / DATA	A TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA
1.	Reference of previous app stability study data of the		h New License	
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			
3.	Documents for the pro- approval from DRAP (in o		M/s Seraph pharma	opy of clearance certificate of specifying import of 10Kg. The invoice is cleared by AD -03-2023.

Sr. No. Shortsomings Despoys by the firm		D 1 41 6
Eval	uation by PEC:	
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
5.	*	Firm has submitted HPLC audit trail reports and 21 CFR compliance certificate
4.		Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.

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

- 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 meropenem2g (Blended with sodium carbonate)
Pharmaceutical form of applied drug	White to almost white powder filled in clear glavials
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. 200 Shenyan Road, Yantian District, Shenzhen Cir Guangdong Province, People's Republic of China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-I template. Firm has summarized information relat to nomenclature, structure, general propertic solubilities, physical form, manufacture description of manufacturing process and control impurities, specifications, analytical procedures a its validation, batch analysis and justification specification, reference standard, container closury system and stability studies of drug substance a drug product.
Module-III Drug Substance:	Firm has submitted detailed data for drug substandata related to nomenclature, structure, generoperties, solubilities, physical for manufacturers, description of manufacturing proceand controls, impurities, specifications, analytic procedures and its validation, batch analysis a justification of specification, reference standar container closure system and stability studies of dr substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batch of drug substance.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutic development, manufacture, manufacturing process and process control, process validation protocolocontrol of excipients, control of drug produspecifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or material container closure system and stability.
Pharmaceutical Equivalence and Comparative	Firm has submitted results of pharmaceutic
Dissolution Profile	equivalence for the quality tests for their produ against Meronem 2g Injection.

	STABILITY STUDY DATA					
Manufacturer of API		urer 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.		lo.	8MT2211102			
	Description of Pack (Container closure system)		Glass vial			
Stab	ility S	torage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time	e Peri	od	Real time: 6 months Accelerated: 6 months			
Freq	uency	1	Accelerated: 0, 1, 2, 3 Real Time: 0, 3, 6 (Mo			
Batc	h No.		NMT-001	NMT-002	NMT-003	
Batc	h Size	e	250 vials	250 vials	250 vials	
Man	ufactı	ıring Date	05-2023	05-2023	05-2023	
		itiation	19-05-2023	19-05-2023	19-05-2023	
No.	of Bat	tches		03		
	DO	OCUMENTS / DATA	TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA	
1.		erence of previous appr fility study data of the f	oval of applications wit	h New License		
2.			Firm has submitted c	Firm has submitted copy of manufacturing license (No. Yue20160126) valid till 08-09-2025.		
3.				dated 19-12-2022 s	Firm has submitted copy of clearance certificate dated 19-12-2022 specifying import of 60Kg meropenem for injection.	
4.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		s, batches along with chr	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.		
5.		npliance Record of HI t trail reports on produ		Firm has submitted that CFR compliant.	at their HPLC system is not 21	
6.					cord of digital data logger for lity monitoring of real time and nambers.	
Eval	uatio	n by PEC:				
C	NT.	Chanta		Dogmo 1- 41 6	_	
Sr. 1.	NO	Submit differential	fee since the applied	Response by the firm	Firm has not differential fee	
			registered in Pakistan.	. I IIII IIII IIII IIII IIII IIII	201 100	
2. Submit specifications from drug product ma		Submit specifications	s of the drug substance			
3.	3. Submit analytical p		procedure of the drug product manufacturer in			
4. Submit verification s procedure for testing		Submit verification s procedure for testin performed by drug p	tudies of the analyticang of drug substance broduct manufacturer in			

	which Firm has submitted details of reference product
pharmaceutical equivalence is con	ducted against which pharmaceutical equivalence was
since the applied formulation is n	ot yet conducted.
registered in Pakistan.	

- 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.

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 Ove	erall 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 Subst	ance:	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 Dru		Firm has submitted stability study data of 3 batches	
(Conditions & duration	•	of drug substance.	
Module-III Drug Produ	Ct:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
Pharmaceutical Equiv Dissolution Profile	alence and Comparative	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 product	validation/verification of	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.	
STABILITY ST		UDY DATA	
Manufacturer of API	Suleshvari Pharma Plot I Bharuch (Gujarat), India	No: 6012/1, GIDC Estate, Ankleshwar – 393002 Dist.:	
API Lot No.	23/SVMC/004		
Description of Pack (Container closure system)	Alu-alu blister pack		
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
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	
Bato	ch Size	1000 Tablet	1000 Tablet	1000 Tablet	
Man	nufacturing Date	07-2023	07-2023	07-2023	
Date	e of Initiation	12-07-2023	12-07-2023	12-07-2023	
No.	of Batches		03		
	DOCUMENTS / DATA	A TO BE PROVIDED A	LONG WITH STABI	LITY STUDY DATA	
1.	Reference of previous app stability study data of the		New License		
2.	Approval of API/ DML/ manufacturer issued by authority of country of or	concerned regulatory		opy of GMP certificate issued ontrol Administration Gujrat 6-09-2024.	
3.	Documents for the proapproval from DRAP (in			opy of clearance certificate of specifying import of 100Kg ated 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 H audit trail reports on production		Firm has submitted HPLC audit trail reports and 21 CFR compliance certificate		
6.	Record of Digital data lo humidity monitoring of time and accelerated)		temperature and humid	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	
Eva	luation by PEC:				
С	NT CI .		D 1 (1 6)		
1.		from Seraph pharma ed commercial invoice is	Response by the firm Firm has submitted co		
•	proposed shelf life and the registration applic	l on accelerated studies ation. form process validation	for six months as per th	stability studies throughout ne commitment submitted in ns per the commitment	
120.	Name, address of App Authorization Holder	licant / Marketing	M/s Biogen Life Scie Rawat	eces 8-KM, Chak Beli Road,	
	Name, address of Manu	facturing site.	M/s Biogen Life Scie Rawat	eces 8-KM, Chak Beli Road,	
	Status of the applicant			e of the above (contract giver)	
	GMP status of the firm N		New License was granted on 14-02-2020. Firm has submitted copy of GMP certificate based on the inspection dated 01-06-2023.		

section.

Evidence of approval of manufacturing facility

Firm has submitted copy of letter of issuance of DML dated 14-02-2020 specifying Tablet (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. 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.		
	Dissolution Profile		equivalence for all the against Neovel Tablet Firm has submitted re	results of pharmaceutical equality tests for their product of Seraph Pharma. sults of kinetic binding studies inst Neovel Tablet of Seraph	
	Analytical method vaproduct	alidation/verification o		erification studies of the drug ical method validation of the	
		STABILITY S	TUDY DATA		
Manı	ufacturer of API	Suleshvari Pharma Plot No: 6012/1, GIDC Estate, Ankleshwar – 393002 Dist.: Bharuch (Gujarat), India.			
API	Lot No.	23/SVMC/004			
	ription of Pack tainer closure system)	Alu-alu blister pack			
Stabi	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	uency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batcl	h No.	SM034	SM035	SM036	
Batcl	h Size	1000 Tablet	1000 Tablet	1000 Tablet	
Manı	ufacturing Date	07-2023	07-2023	07-2023	
Date	of Initiation	12-07-2023	12-07-2023	12-07-2023	
No. o	of Batches		03		
			ALONG WITH STABI	LITY STUDY DATA	
1.	Reference of previous appropriate stability study data of the f		h New License		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			ontrol Administration Gujrat	
3.			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 attested respective docume Raw data sheets, COA, sur	ents like chromatograms			
5.	Compliance Record of Hi audit trail reports on produ		Firm has submitted HPLC audit trail reports and 21 CFR compliance certificate		
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		al temperature and humic		
Eval	Evaluation by PEC:				
C.	No Shortcomings		Response by the firm	,	
Sr. No Shortcomings Response by the firm			I		

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

- 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	
	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 HC137.5 mg Paracetamol325 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 Over	rall 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 Substar	nce:	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 (Conditions & duration of		Firm has submitted stability study data of 3 batches of drug substance.
Module-III Drug Produc	•	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equival Dissolution Profile	ence and Comparative	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 va	alidation/verification of	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.
	STABILITY ST	UDY DATA
Manufacturer of API	Nagar, Kasur -55050 Pu Tramadol: M/s. VIRUI	na (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool njab, Pakistan. PAKSHA ORGANIC LIMITED, Plot No. B-4 IDA, d -500037, Telengana, India.
API Lot No.	Paracetamol: PGS21-10 Tramadol: BTDHC082	
Description of Pack (Container closure system)	Alu-alu blister pack	
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$	
Time Period	Real time: 6 months Accelerated: 6 months	

Frequency		1	Accelerated: 0, 3, 6 (Meal Time: 0, 3, 6 (Meal			
Batch No.			PT001	PT002	PT003	
Batch Size		 e	1000 Tablet	1000 Tablet	1000 Tablet	
Manufacturing Date		uring Date	06-2023	06-2023	06-2023	
		itiation	03-06-2023	03-06-2023	03-06-2023	
No.	of Ba	tches		03		
	Do	OCUMENTS / DATA	TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA	
1.	Reference of previous approval of applications with stability study data of the firm (if any)			h New License		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		y certificate issued on th 03-2023 Tramadol: Firm ha	e basis of inspection dated 03- s submitted copy of GMP Drug Control Administration		
3.	Documents for the procurement of API with approval from DRAP (in case of import).			commercial invoice 540kg paracetamol by Tramadol: Firm has so commercial invoice	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.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			mplete record of testing of all data sheets, COA and		
5.	Con		PLC software 21CFR	· ·	PLC audit trail reports and 21 icate	
6.	hum	e e	ger for temperature an stability chambers (rea		cord of digital data logger for lity monitoring of real time and nambers.	
Eval	uatio	n by PEC:				
G	NT.	Cl4		D 1 41 . 6		
1.	No	manufacturer of th	nding brand name and e comparator product maceutical equivalence conducted.	t	tails of comparator product.	
2.		Submit valid GMP manufacturer.	certificate of both AP	certificate issued on to 03-03-2023 Tramadol: Firm ha certificate issued by begovernment of Telang	has submitted copy of GMP the basis of inspection dated s submitted copy of GMP Drug Control Administration than dated 27-03-2019.	
3.	3. Submit loan letter from Biogen pharms because the submitted commercial invoice i			ppy of loan letter		

Decision: Approved.

for Biogen pharma.

- 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 HCl75mg Paracetamol650mg	
	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 Substa	nce:	data related to nom properties, solubi manufacturers, descrip and controls, impurit procedures and its v justification of speci	etailed data for drug substance enclature, structure, general lities, physical form, otion of manufacturing process ies, specifications, analytical alidation, batch analysis and dification, reference standard, em and stability studies of drug	
Stability Studies of Dru (Conditions & duration		Firm has submitted st of drug substance.	ability study data of 3 batches	
Module-III Drug Produc	ct:	its description, condevelopment, manufation and process control, control of excipients specifications, analytical procedures,	ata of drug product including omposition, pharmaceutical acture, manufacturing process process validation protocols, s, control of drug product, acal procedures, validation of batch analysis, justification of ence standard or materials, em and stability.	
Pharmaceutical Equiva Dissolution Profile	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 v product	alidation/verification o		erification studies of the drug ical method validation of the	
	STABILITY S	TUDY DATA		
Manufacturer of API	Nagar, Kasur -55050 F Tramadol: M/s. VIR	Punjab, Pakistan.	ter, Head Balloki Road, Phool LIMITED, Plot No. B-4 IDA, India.	
API Lot No.	Paracetamol: PGS21- Tramadol: BTDHC08			
Description of Pack (Container closure system)	Alu-alu blister pack			
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time Period Real time: 6 months Accelerated: 6 months				
Frequency Accelerated: 0, 3, 6 (Mor Real Time: 0, 3, 6 (Mont		*		
Batch No. PT004		PT005	PT006	
Batch Size 1000 Tablet		1000 Tablet	1000 Tablet	
Manufacturing Date	Manufacturing Date 06-2023		06-2023	
Date of Initiation	03-06-2023	03-06-2023	03-06-2023	
No. of Batches		03		
DOCUMENTS / DATA	A TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA	

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New License
2.	**	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	Firm has submitted details of comparator product.
	and CDP studies are conducted.	
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

- 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: Isotretinoin40mg
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

	Module-III Drug Product: Fit day and construct of the second state of the second stat		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. 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 va product	alidation/verification of	Firm has submitted ve substance and the drug	erification studies of the drug product.
		STABILITY ST	UDY DATA	
Man	ufacturer of API		nengchem Pharmaceutic Hechuan District, Change	al Co. Ltd No. 666 Rongjun qin China.
API	Lot No.	20220418		
Description of Pack (Container closure system) Alu-alu blister		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 (Accelerated: 0, 3, 6 (Mor Real Time: 0, 3, 6 (Mor		
Batcl	n No.	T-012	T-013	T-014
Batcl	n Size	1000 Capsule	1000 Capsule	1000 Capsule
Man	ufacturing Date	04-2023	04-2023	04-2023
Date	of Initiation	17-04-2023	17-04-2023	17-04-2023
No. o	of Batches		03	
	DOCUMENTS / DATA	TO BE PROVIDED A	LONG WITH STABII	LITY 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 codated 11-02-2026	opy of Drug Import License
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		batches along with raw summary data sheets.	nplete record of testing of all data sheets, COA and
5.	5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing		NA	

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

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	Submit details including brand name and	Submitted by the firm
	manufacturer of the comparator product	
	against which pharmaceutical equivalence	
	and CDP studies are conducted.	
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.

- 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: Cholecalciferol7.5mg (300000IU)
	Pharmaceutical form of applied drug	Sterile clear and colourless oily solution filled in glass ampoules

Pl	harmacotherapeutic Gro	oup of (API)	Vitamin
Reference to Finished product		oduct specifications	BP
Pı	roposed Pack size		1's
Pı	Proposed unit price		As per SRO
T	The status in reference regulatory authorities		AIFA Italy Approved
Fo	For generic drugs (me-too status)		NA
N	ame and address of AP	I manufacturer.	Sichuan Yuxin Pharmaceutical Co., Ltd. No. 51, West Section of Changjiang Road, Shifang Economic Development Zone (South District) Shifang city, Sichuan Province China.
M	Iodule-II (Quality Overa	all 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.
M	Iodule-III Drug Substan	ice:	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.
	tability Studies of Drug Conditions & duration o		Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
M	Iodule-III Drug Product	:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Dissolution Profile		ence and Comparative	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against vitamin D3 300000 IU injection
		lidation/verification of	Firm has submitted verification studies of the drug substance and validation studies of the drug product.
		STABILITY ST	UDY DATA
Road, Shifang Economic			eutical Co., Ltd. No. 51, West Section of Changjiang ic Development Zone (South District) Shifang city,
API Lot No. CH22041003		CH22041003	
Description of Pack Glass ampoule		Glass ampoule	

(Container closure system)					
Stability Storage Condition Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / \text{Accelerated: } 40^{\circ}\text{C} \pm 2^{\circ}\text{C}$					
		Real time: 6 months Accelerated: 6 months			
Freq	uency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batc	h No.	T001	T002	T003	
Batc	h Size	1000 ampoules	1000 ampoules	1000 ampoules	
Man	ufacturing Date	03-2023	03-2023	03-2023	
Date	of Initiation	24-03-2023	24-03-2023	24-03-2023	
No. o	of Batches		03		
	DOCUMENTS / DATA	TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA	
1.	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.			ppy of DML issued by CFDA	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		ith Firm has submitted co Goods Declaration	py of commercial invoice and	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		ns, batches along with raw	mplete record of testing of all data sheets, COA and	
5.	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)			cord of digital data logger for lity monitoring of real time and nambers.	
Evaluation by PEC:					

Evaluation by PEC:

(Container closure system)

• 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
	\square Is involved in none of the above (contract given
GMP status of the firm	Firm has been granted new license dated 26-10-20
	for following sections: • Tablet (General) section
	 Liquid injection vial (General) section
	Liquid injection ampoule (general) section
	Capsule (Cephalosporin) section
	• Dry powder for injection (cephalosporin) sect
	• Dry powder for suspension (cephalosposection
	• Cream / ointment (General) section
	• Eye drops (General) section.
Evidence of approval of manufacturing facility	Firm has been granted new license dated 26-10-20
	for following sections:
	• Tablet (General) section
	Liquid injection vial (General) sectionLiquid injection ampoule (general) section
	Capsule (Cephalosporin) section
	• Dry powder for injection (cephalosporin) sect
	• Dry powder for suspension (cephalospo
	section
	 Cream / ointment (General) section Eye drops (General) section.
Status of application	☐ New Drug Product (NDP)
Status of approacion	☐ New Brug Froduct (NDF) ☐ 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 HealthC Pharmaceuticals Inc. USA (USFDA Approved)
For generic drugs (me-too status)	Ciproxin Tablet 250mg of M/s Bayer Pakistan (I Limited (Reg # 010118)
Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 F. Ferozepur Road, Lahore.

Module-II (Quality Over			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 Substar	nce:	substance data relate general properties, manufacturers, descri and controls, impuri procedures and its v justification of spec	detailed data for both drug ed to nomenclature, structure, solubilities, physical form, ption of manufacturing process ties, specifications, analytical validation, batch analysis and diffication, reference standard, em and stability studies of drug	
Stability Studies of Drug		Firm has submitted st of drug substance.	tability study data of 3 batches	
*	(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 Equival Dissolution Profile	ence and Comparativ	equivalence for the against Ciptec tablet	esults of CDP for their product	
Analytical method va product	llidation/verification	analytical method for	d report of verification of	
	STABILITY S			
Manufacturer of API		Kot Nabi Bukshwala, 34 I	Km, Ferozepur Road, Lahore.	
API Lot No.	00510011/022/2023			
Description of Pack (Container closure system)	Alu-Alu blister			
Stability Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2$			
Time Period	Real time: 6 months Accelerated: 6 months	S		
Frequency	Accelerated: 0, 3, 6 (Meal Time: 0, 3, 6 (Meal			
Batch No.	T001	T002	T003	

Batch Size		1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date 12-2		12-2023	12-2023	12-2023
Date of Initiation 09-12-2023		09-12-2023	09-12-2023	
No. of Batches		03		
	DOCUMENTS / DATA	A TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA
1.	Reference of previous approval of applications with stability study data of the firm (if any)		h New License	
2.	manufacturer issued by concerned regulatory authority of country of origin.		y by Additional Director	DRAP, Lahore dated 22-11 ficate was granted based of
3.				copy of invoice for 5K loride dated 01-12-2023 from
4.	Data of stability batche attested respective docum Raw data sheets, COA, su	ents like chromatograms	-	mplete record of testing of all omatograms, raw data sheets, a sheets.
5.	Compliance Record of H audit trail reports on production		& Not submitted by the f	irm
6.	Record of Digital data lo humidity monitoring of time and accelerated)			cord of digital data logger for ity monitoring of real time an ambers.
Evalu	uation by PEC:		·	
	~		submitted data is for 3 mo	
•	proposed shelf life and the registration applic Manufacturer will per submitted in the regist	l on accelerated studies ation. form process validatio tration application. Chairman for issuance	s for six months as per the solution of first three batches a solution of Registration Letter up	stability studies throughout ne commitment submitted in s per the commitment oon submission of 6 th month
174	Authorization Holder			outicals (CMC Dut) I 4d Dla
126.	Authorization Holder	meant / Walketing		euticals (SMC-Pvt) Ltd. Plo Estate, K.L.P Road, Rahin
126.	Name, address of Manu		No. 95-A, Industrial Yar Khan. M/s Naeem Pharmac	
126.			No. 95-A, Industrial Yar Khan. M/s Naeem Pharmac No. 95-A, Industrial E Khan. Manufacturer Importer	Estate, K.L.P Road, Rahin euticals (SMC-Pvt) Ltd. Plo

• 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

			and controls, impurit procedures and its v justification of speci	ption of manufacturing process ies, specifications, analytical alidation, batch analysis and ification, reference standard, em and stability studies of drug
	Stability Studies of Drug (Conditions & duration of		Firm has submitted st of drug substance.	ability study data of 3 batches
	Module-III Drug Produc	t:	its description, condevelopment, manufation and process control, control of excipients specifications, analytical procedures,	ata of drug product including omposition, pharmaceutical acture, manufacturing process process validation protocols, s, control of drug product, ical procedures, validation of batch analysis, justification of ence standard or materials, em and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile		equivalence for the cagainst Ciptec tablet of	sults of CDP for their product
	Analytical method vaproduct	lidation/verification o	analytical method for	report of verification of
	•	STABILITY S	TUDY DATA	
Manu	facturer of API	Pharmagen Limited. K	ot Nabi Bukshwala, 34 K	Km, Ferozepur Road, Lahore.
API I	Lot No.	00510011/022/2023		
	ription of Pack ainer closure system)	Alu-Alu blister		
Stabil	lity Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequ	nency	Accelerated: 0, 3, 6 (Macelerated: 0, 3, 6 (*	
Batch	No.	T001	T002	T003
Batch	Size	1500 Tablet	1500 Tablet	1500 Tablet
Manu	facturing Date	12-2023	12-2023	12-2023
Date	of Initiation	09-12-2023	09-12-2023	09-12-2023
No. o	f Batches		03	
	DOCUMENTS / DATA	TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA
1.	Reference of previous appr stability study data of the f		h New License	
2.	manufacturer issued by concerned regulatory authority of country of origin.		y by Additional Director	r DRAP, Lahore dated 22-11- ificate was granted based on

3.	Documents for the procurement of API wit approval from DRAP (in case of import).	h 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 chromatogram Raw data sheets, COA, summary data sheets etc.	
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 an humidity monitoring of stability chambers (retime and accelerated)	
Eval	uation by PEC:	
	Submit 6 month's stability study data since the	submitted data is for 3 months only.
•	the registration application. Manufacturer will perform process validation	s for six months as per the commitment submitted in n of first three batches as per the commitment
127.	 the registration application. Manufacturer will perform process validatio submitted in the registration application. Board authorized its Chairman for issuance stability study data. 	n of first three batches as per the commitment of Registration Letter upon submission of 6 th month M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim
127.	 the registration application. Manufacturer will perform process validation submitted in the registration application. Board authorized its Chairman for issuance stability study data. Name, address of Applicant / Marketing 	n of first three batches as per the commitment of Registration Letter upon submission of 6 th month M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan. M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No.
127.	the registration application. Manufacturer will perform process validation submitted in the registration application. Board authorized its Chairman for issuance stability study data. Name, address of Applicant / Marketing Authorization Holder	of Registration Letter upon submission of 6 th month M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan.

Evidence of approval of manufacturing facility

Status of application

Firm has been granted new license dated 26-10-2023

Dry powder for injection (cephalosporin) sectionDry powder for suspension (cephalosporin) section

Liquid injection vial (General) sectionLiquid injection ampoule (general) section

• Capsule (Cephalosporin) section

• Cream / ointment (General) section

• Eye drops (General) section.

☐ New Drug Product (NDP)

for following sections:Tablet (General) section

	☐ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale
	☐ Export sale
D. W. Harris G. L. C.	☑ Domestic and Export sales
· ·	Tracking ID. PS5-N5B-RGGN: 17-04-2024
	PKR 30,000/-: 21-03-2024
	AZINEM 250mg tablets
\mathcal{E}	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)
	Orzit Tablet 250mg of M/s Martin Dow (Re 057294)
	M/s Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Bal Road, Phool Nagar, Kasur -55050 Punjab, Pakista
	Firm has submitted QOS as per WHO QOS template. Firm has summarized information relate nomenclature, structure, general proper solubilities, physical form, manufacturers, descrip of manufacturing process and controls, impuri specifications, analytical procedures and its validat batch analysis and justification of specificat reference standard, container closure system stability studies of drug substance and drug production.
	Firm has submitted detailed data for both of substance data related to nomenclature, struct general properties, solubilities, physical for manufacturers, description of manufacturing product and controls, impurities, specifications, analyst procedures and its validation, batch analysis justification of specification, reference stand container closure system and stability studies of c substance.
	Firm has submitted stability study data of 3 batchedrug substance.
	Firm has submitted data of drug product including
	description, composition, pharmace development, manufacture, manufacturing process process control, process validation protocols, confexcipients, control of drug product, specifical analytical procedures, validation of analyprocedures, batch analysis, justification specifications, reference standard or materials.

Dissolut	Dissolution Profile		against Azikam Tab Firm has submitted in	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	
Analytic product	Analytical method validation/verification of product		method for the drug	substance. report of verification of analytical	
		STABILITY	Y STUDY DATA		
Manufacturer of	f API	M/s Citi Pharma (P Kasur -55050 Punjab		Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, akistan	
API Lot No.		AZM2311001	M2311001		
Description of I (Container closs		Alu-Alu blister			
Stability Storage	e Condition	Real time : 30°C ± 2° Accelerated: 40°C ±			
Time Period		Real time: 6 months Accelerated: 6 month	hs		
Frequency		Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N			
Batch No.		T001	T002	T003	
Batch Size		1500 Tablet	1500 Tablet	1500 Tablet	
Manufacturing 1	Date	11-2023	11-2023	11-2023	
Date of Initiatio	n	16-11-2023	16-11-2023	16-11-2023	
No. of Batches			03		
DOCU	MENTS / DAT	A TO BE PROVIDE	ED ALONG WITH STA	ABILITY STUDY DATA	
		pproval of application of the firm (if any)	ns New License.		
manufactu		concerned regulato		copy of GMP certificate dated 09- e basis of inspection dated 03-03-	
	Documents for the procurement of API with approval from DRAP (in case of import).			d copy of commercial invoice of 10Kg Azithromycin dihydrate	
attested chromatog	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		ke batches along with U	V spectra, raw data sheets, COA	
_	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)			nidity monitoring of real time and		
Evaluation by	PEC:				
• Submit	6 month's stabi	lity study data since the	he submitted data is for 3	3 months only.	
Decision: Appr	oved.				

- 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.

	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
		☐ 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 unit price		As per SRO
	The status in reference i	regulatory authorities	(USFDA Approved)
	For generic drugs (me-t	oo status)	Orzit Tablet of M/s Martin Dow
	Name and address of Al	PI manufacturer.	M/s Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan
	Module-II (Quality Ove	rall 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: Stability Studies of Drug Substance (Conditions & duration of Stability studies)		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.
			Firm has submitted stability study data of 3 batches of drug substance.
	Module-III Drug Produc	et:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 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
			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 S'		TUDY DATA
Manufa	acturer of API	M/s Citi Pharma (Pvt.) Kasur -55050 Punjab, P	Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Pakistan
API Lo	ot No.	AZM2311001	
	ption of Pack iner closure system)	Alu-Alu blister	
		Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$	65% ± 5%RH

		Accelerated: 40°C ±	2°C / 75% ± 5%RH	
Time	Time Period Real time: 6 months Accelerated: 6 months		ns	
Frequency Accelerated: 0, 3, 6 (More Real Time: 0, 3, 6 (More Real Time				
Batc	h No.	T001	T002	T003
Batc	h Size	1500 Tablet	1500 Tablet	1500 Tablet
Man	ufacturing Date	11-2023	11-2023	11-2023
Date	of Initiation	16-11-2023	16-11-2023	16-11-2023
No.	of Batches		03	
	DOCUMENTS / DAT	A TO BE PROVIDE	D ALONG WITH STA	BILITY STUDY DATA
1.	Reference of previous a with stability study data of		ns New License.	
2.				opy of GMP certificate dated 09- e basis of inspection dated 03-03-
3.				copy of commercial invoice of 10Kg Azithromycin dihydrate
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		ke batches along with U	V spectra, raw data sheets, COA	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		& Not applicable. Our F	IPLC systems are not 21
6.				idity monitoring of real time and
Eval	uation 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

12	29.	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 Soidum250mg
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.	
	(Conditions & duration of Stability studies) Module-III Drug Product:		Firm has submitted stability study data of 3 batches of drug substance as per Zone II conditions Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
	Pharmaceutical Equiva Dissolution Profile	lence and Comparative		
	Analytical method vaproduct	alidation/verification of	Firm has submitted versubstance and the drug	erification studies of the drug product.
		STABILITY ST	TUDY DATA	
Manu	facturer of API			xin Pharmaceutical Co., Ltd. opment Zone, Feixian, Linyi,
API I	Lot No.	12C0302104005		
	ription of Pack tainer closure system)	Glass vial		
Stabil	lity Storage Condition	Real time : 30°C ± 2°C Accelerated: 40°C ± 2°C		
		Real time: 6 months Accelerated: 6 months		
Frequ	nency	Accelerated: 0, 3, 6 (MorReal Time: 0, 3, 6 (Mor		
Batch	ı No.	TR-CEP-66	TR-CEP-67	TR-CEP-68
Batch	Size	1719 vials	1719 vials	1719 vials
Manu	ifacturing Date	09-2021	09-2021	09-2021
Date	of Initiation	17-09-2021	17-09-2021	17-09-2021
No. o	f Batches		03	
	DOCUMENTS / DATA		T	LITY STUDY DATA
1.	Reference of previous appr stability study data of the f			
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			copy of GMP certificate of the basis of inspection dated 22-
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 Hi audit trail reports on produ			

6.	Record of Digital data logger for temperature and			
0.	humidity monitoring of stability chambers (real			
	time and accelerated)			
Evalı	nation by PEC:			
Sr. l	No Shortcomings communicated		Response by the firm]
1.	Evidence of approval of applied formula	tion in		-
	reference regulatory authorities which were add			
	Registration Board in its 275 th meeting.			
2.	Submit specifications as well as analytical me			
	the drug substance from the drug product manu	facturer		
	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 g	uidance		
	document approved by Registration Board	1 .		-
4.	Submit COA of reference standard used in the	anaiysis		
5.	of drug substance. Submit stability study data of 3 batches of AP	I ac nor		-
٦.	zone IV-A conditions.	i as per		
6.	Specify the fill weight of the product per vial.			
7.	Submit drug excipient compatibility studies, sir	ice vour		-
, .	qualitative composition is different from	•		
	reference product.			
8.	Submit report of pharmaceutical equivalence st	udies.		
9.	Submit preservative effectiveness studies			
	Submit microbial attributes of the drug product			
10	Submit compatibility studies in section 3.2.P.2.			
10.	Submit stability study data of drug product in			
	3.2.P.8 as per the 6 points checklist specified			
	CTD guidance document. Moreover, the stabil	•		
	shall be submitted in proper sequence with tag differentiate between data of each time point an			
11.	Submit BMR of three stability batches.	u baten.		-
<u> </u>	ion: Registration Board deferred the case for sub	mission	of ronly to the above sited shortsomin	oc.
130.	Name, address of Applicant / Marketing	1	uratech Pharma pvt Ltd 35-Km, Mu	
150.	Authorization Holder	Road, l	<u>=</u>	ıtan
	Name, address of Manufacturing site.	M/s Cu Lahore	ratech Pharma pvt Ltd 35-Km, Multan R	oad,
	Status of the applicant	⊠ Man □ Impo	ufacturer orter	
		☐ Is in	volved in none of the above (contract give	/er)
	GMP status of the firm		as submitted copy of GMP certificate issociates of inspection dated 19-02-2020	sued
	Evidence of approval of manufacturing facility	addition following • Dry sections	nas submitted copy of leter of grant nal section dated 22-12-2020 which spec- ng sections: powder for injection (Cephalospo on. sule (Cephalosporin) section.	ifies
		• Dry	powder for suspension (cephalospo	orin)

Status of application

□ New Drug Product (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 Soidum1g
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	

	D	Dissolution Profile				
		nalytical method varioduct	alidation/verification		has submitted vance and the drug	erification studies of the drug g product.
	•		STABILITY S	STUDY I	OATA	
West Side o					gxin Pharmaceutical Co., Ltd. opment Zone, Feixian, Linyi,	
API	Lot 1	No.	12C0302104005			
	•	on of Pack er closure system)	Glass vial			
Stab	ility	Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2$			
Time	e Per	iod	Real time: 6 months Accelerated: 6 months	s		
Freq	uenc	у	Accelerated: 0, 3, 6 (M) Real Time: 0, 3, 6 (M)	,		
Batc	h No).	TR-CEP-10	TR	-CEP-11	TR-CEP-12
Batc	h Siz	ze e	1080 vials	10	80 vials	1080 vials
Man	ufact	turing Date	07-2021	0	7-2021	07-2021
Date	of I	nitiation	09-07-2021	09-	-07-2021	09-07-2021
No.	of Ba	atches			03	
	D	OCUMENTS / DATA	TO BE PROVIDED	ALONG	WITH STABI	LITY STUDY DATA
1.		Ference of previous appropriate study data of the f		th		
2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			agen issued on th			
3.		cuments for the proproval from DRAP (in c		th		
4.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		-			
5.		mpliance Record of HI lit trail reports on produ		&		
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)					
Eval	uatio	on by PEC:				
Sr.	No	Shortcomings comm	unicated		Response by	the firm
1.		Evidence of approv	val of applied formu uthorities which were a		ı	
2 Colonia and Figure 11		11 1 1	41 1	c		

Submit specifications as well as analytical method of the drug substance from the drug product manufacturer

Submit data in section 3.2.S.4.3 as per the guidance

in section 3.2.S.4.1 and 3.2.S.4.2.

document approved by Registration Board

2.

3.

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.	

Decisi	cision: 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: Cephalexin125mg		
	Pharmaceutical form of applied drug	Dry powder for suspension		
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic		
	Reference to Finished product specifications	USP		

Duonagad Dagle siza		As man CDO	
Proposed unit price		As per SRO	
Proposed unit price	1 4 4 4	As per SRO	
The status in reference re	-	USFDA Approved	
For generic drugs (me-to	•	Ceporex suspension by GSK	
Name and address of AF	I manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.	
Module-II (Quality Over	rall 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 Substan	nce:	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 (Conditions & duration of		Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions	
Module-III Drug Produc	t:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
Pharmaceutical Equival Dissolution Profile	ence and Comparative		
Analytical method va	alidation/verification of	Firm has submitted verification studies of the drug substance and the drug product.	
	STABILITY ST	UDY DATA	
Manufacturer of API	Pharmagen Limited. Kot	t Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.	
API Lot No.			
Description of Pack (Container closure system) Glass bottle			
Stability Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Mo	nths)	

	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.		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	
2	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		
1.1	each time point and batch.		
11.	Submit BMR of three stability batches.		
132.	Name, address of Applicant / Marketing	omission of reply to the above cited shortcomings. M/s Curatech Pharma pvt Ltd 35-Km, Multan	
132.	Authorization Holder	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: Cephalexin250mg	
	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	

			_	e standard, container closure tudies of drug substance and	
	Module-III Drug Substance:		data related to nome properties, solubil manufacturers, descrip and controls, impuriti procedures and its va justification of specif	tailed data for drug substance enclature, structure, general ities, physical form, tion of manufacturing process es, specifications, analytical didation, batch analysis and fication, reference standard, m and stability studies of drug	
	Stability Studies of Dru (Conditions & duration			Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions	
Module-III Drug Product:		ct:	its description, co development, manufact and process control, p control of excipients specifications, analytic analytical procedures, l	ta of drug product including omposition, pharmaceutical eture, manufacturing process process validation protocols, control of drug product, cal procedures, validation of batch analysis, justification of nee standard or materials, m and stability.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile		re		
	Analytical method validation/verification of product			Firm has submitted verification studies of the drug substance and the drug product.	
	STABILITY ST		TUDY DATA		
Manu	facturer of API	Pharmagen Limited. K	Kot Nabi Bukshwala, 34 K	m, Ferozepur Road, Lahore.	
API L	ot No.				
	iption of Pack ainer closure system)	Glass bottle			
Stabil	ity Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	ency	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	
Manu	facturing Date	08-2021	08-2021	08-2021	
Date	of Initiation	04-08-2021	04-08-2021	04-08-2021	
No. o	f Batches		03		
	DOCUMENTS / DATA	A TO BE PROVIDED	ALONG WITH STABIL	LITY STUDY DATA	
	Reference of previous app stability study data of the	* *	h		
2.					

3.		cuments for the procurement of API with broval from DRAP (in case of import).		
4.	atte	a of stability batches will be supported by sted respective documents like chromatograms, w data sheets, COA, summary data sheets etc.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing			
6.	hun	cord of Digital data logger for temperature and midity monitoring of stability chambers (real e and accelerated)		
Eval	uatio	on by PEC:		
Sr.	No	Shortcomings communicated		Response by the firm
1.	- 10	Submit label claim of applied product in lin	e with the	
		reference product along with submission of req		
2.		Submit specifications as well as analytical met		
		drug substance from the drug product manu		
		section 3.2.S.4.1 and 3.2.S.4.2.	racturer in	
3.		Submit data in section 3.2.S.4.3 as per the	guidance	
] 3.		document approved by Registration Board	guidance	
4.		Submit COA of relevant batch of drug substar	ice used in	
		product development and stability studies from		
		substance as well as drug product manufacturer		
		3.2.S.4.4.	in section	
5.		Justify the use of compacted API to m	anufacture	
] 3.		suspension	anuracture	
6.		Submit COA of reference standard used in the	analysis of	
0.		drug substance.	unary sis or	
7.		Submit drug excipient compatibility studies,	since vour	
′ ·		qualitative composition is different from that o		
		product.	1 1010101100	
8.		Submit report of pharmaceutical equivalence	and CDP	
		studies.	W110 021	
9.		Submit preservative effectiveness studies		
		Submit microbial attributes of the drug product		
10		Submit compatibility studies in section 3.2.P.2.		
10.		Submit stability study data of drug product		
10.		3.2.P.8 as per the 6 points checklist specified i		
		guidance document. Moreover, the stability da		
		submitted in proper sequence with tagging to d		
		between data of each time point and batch.	incicintate	
11.		Submit BMR of three stability batches.		
	•	· · · · · · · · · · · · · · · · · · ·	• • A	
Decis	sion	: Registration Board deferred the case for sub	mission of r	reply to the above cited shortcomings.
133.		Name, address of Applicant / Marketing		tech Pharma pvt Ltd 35-Km, Multan
			Road, Lah	
	N	Jame, address of Manufacturing site.	M/s Curate Lahore	ech Pharma pvt Ltd 35-Km, Multan Road,
	S	tatus of the applicant	⊠ Manufa	cturer
			☐ Importe	
			⊔ Is involv	ved in none of the above (contract giver)
	G	GMP status of the firm		ubmitted copy of GMP certificate issued s 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: Cefadroxil500mg	
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	

			composition, pharmaceutical facture, manufacturing process I, process validation protocols, nts, control of drug product, vical procedures, validation of s, batch analysis, justification of trence standard or materials, stem and stability.	
Pharmaceutical Equiva Dissolution Profile	lence and Comparati	ve		
Analytical method validation/verification of product			Firm has submitted verification studies of the drug substance and the drug product.	
	STABILITY S	STUDY DATA		
Manufacturer of API	Pharmagen Limited. 1	Kot Nabi Bukshwala, 34	Km, Ferozepur Road, Lahore.	
API Lot No.				
Description of Pack (Container closure system)	Blister			
Stability Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2$			
Time Period	Real time: 6 months Accelerated: 6 month	S		
Frequency	Accelerated: 0, 3, 6 (MReal Time: 0, 3, 6 (MReal Ti			
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				
	Reference of previous approval of applications with stability study data of the firm (if any)			
manufacturer issued by	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		1.0	
_	Documents for the procurement of API with approval from DRAP (in case of import).			
attested respective docume	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 Hi audit trail reports on produ		&		
	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real			
Evaluation by PEC:				
Sr. No Shortcomings communicated Response by the firm				
	of applied product in		and by the III III	
	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	
4.	document approved by Registration Board 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.	

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 The proposed proprietary name / brand name Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Pharmaceutical form of applied drug Pharmacotherapeutic Group of (API) Reference to Finished product specifications Proposed Pack size Proposed unit price The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Module-II (Quality Overall Summary) Module-III (Drug Substance:	PKR 30,000/-: 28-11-2022 ROXI 125mg/5ml 60ml Dry Powder Suspension Each 5ml Reconstituted Suspension Contains: Cefadroxil Monohydrate125mg Dry powder for suspension Cephalosporin Antibiotic USP As per SRO As per SRO Could not be confirmed Duricef suspension by GSK Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Pharmaceutical form of applied drug Pharmacotherapeutic Group of (API) Reference to Finished product specifications Proposed Pack size Proposed unit price The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Module-II (Quality Overall Summary)	Each 5ml Reconstituted Suspension Contains: Cefadroxil Monohydrate125mg Dry powder for suspension Cephalosporin Antibiotic USP As per SRO As per SRO Could not be confirmed Duricef suspension by GSK Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,
Pharmacotherapeutic Group of (API) Reference to Finished product specifications Proposed Pack size Proposed unit price The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Module-II (Quality Overall Summary)	Cephalosporin Antibiotic USP As per SRO As per SRO Could not be confirmed Duricef suspension by GSK Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,
Reference to Finished product specifications Proposed Pack size Proposed unit price The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Module-II (Quality Overall Summary)	USP As per SRO As per SRO Could not be confirmed Duricef suspension by GSK Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,
Proposed Pack size Proposed unit price The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Module-II (Quality Overall Summary)	As per SRO Could not be confirmed Duricef suspension by GSK Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,
Proposed unit price The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Module-II (Quality Overall Summary)	As per SRO Could not be confirmed Duricef suspension by GSK Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,
The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Module-II (Quality Overall Summary)	Could not be confirmed Duricef suspension by GSK Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,
For generic drugs (me-too status) Name and address of API manufacturer. Module-II (Quality Overall Summary)	Duricef suspension by GSK Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,
Name and address of API manufacturer. Module-II (Quality Overall Summary)	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,
Module-II (Quality Overall Summary)	Ferozepur Road, Lahore. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,
	template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,
Module-III Drug Substance:	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.
	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 ST	
Manufacturer of API Pharmagen Limited. Kot	UDY DATA

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)			
Bato	ch No.	TR-CEP-18	TR-CEP-19	TR-CEP-20	
Bato	ch Size	600 bottles	600 bottles	600 bottles	
Man	ufacturing Date	07-2021	07-2021	07-2021	
Date of Initiation		29-07-2021	29-07-2021	29-07-2021	
No.	No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED AI			ALONG WITH STABI	LITY STUDY DATA	
1.	Reference of previous approval of applications with stability study data of the firm (if any)		th		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			1.0	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		ith		
4.	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 H audit trail reports on produ		&		
6.	Record of Digital data log humidity monitoring of time and accelerated)	1			

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 275 th 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.	

Designary Designation Deared deformed the ease for submission of really to the above sited shortcomings			
sion: Registration Board deferred the case for submission of reply to the above cited shortcomings. Name, address of Applicant / Marketing M/s Curatech Pharma pvt Ltd 35-Km, Multa			
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 Monohydrate250mg		
Pharmaceutical form of applied drug	Dry powder for suspension		
Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic		
Reference to Finished product specifications	USP		
	Name, address of Applicant / Marketing Authorization Holder Name, address of Manufacturing site. Status of the applicant GMP status of the firm Evidence of approval of manufacturing facility Status of application Intended use of pharmaceutical product Dy. No. and date of submission Details of fee submitted The proposed proprietary name / brand name Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Pharmacotherapeutic Group of (API)		

Duomonad Dankaina		As man CDO
Proposed Pack size		As per SRO
Proposed unit price	1 4 4 4	As per SRO
The status in reference re	-	USFDA Approved
For generic drugs (me-to	•	Duricef suspension by GSK
Name and address of AF	I manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
Module-II (Quality Over	rall 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 Substan	nce:	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 (Conditions & duration of		Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A conditions
Module-III Drug Produc	t:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equival Dissolution Profile	ence and Comparative	
Analytical method va	alidation/verification of	Firm has submitted verification studies of the drug substance and the drug product.
	STABILITY ST	UDY DATA
Manufacturer of API	Pharmagen Limited. Kot	t Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
API Lot No.		
Description of Pack (Container closure system) Glass bottle		
Stability Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency Accelerated: 0, 3, 6 (Mor		nths)

	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.	**	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.	

12	, , , , , , , , , , , , , , , , , , ,		
	ecision: 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: Cephradine125mg	
	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,	

			description of manufal impurities, specification its validation, batch specification, reference	al form, manufacturers, acturing process and controls, ons, analytical procedures and analysis and justification of the standard, container closure tudies of drug substance and
	Module-III Drug Substa	ance:	data related to nom properties, solubi manufacturers, descrip and controls, impurit procedures and its va- justification of speci	tailed data for drug substance enclature, structure, general lities, physical form, ation of manufacturing process ies, specifications, analytical alidation, batch analysis and fication, reference standard, and stability studies of drug
	Stability Studies of Dru (Conditions & duration			ability study data of 3 batches er refrigerated conditions.
	Module-III Drug Product:		Firm has submitted daits description, condevelopment, manufal and process control, control of excipients specifications, analytical procedures,	ata of drug product including omposition, pharmaceutical cture, manufacturing process process validation protocols, s, control of drug product, cal procedures, validation of batch analysis, justification of nce standard or materials,
	Analytical method v	validation/verification of	Firm has submitted versubstance and the drug	erification studies of the drug
STABILITY ST		UDY DATA		
Manu	facturer of API	Pharmagen Limited. Ko	t Nabi Bukshwala, 34 K	m, Ferozepur Road, Lahore.
API I	Lot No.			
Description of Pack (Container closure system) Glass bottle				
Stabil	ity Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequency Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mon				
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	07-2021
Date	of Initiation	26-07-2021	26-07-2021	26-07-2021
No. o	f Batches		03	
	DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			LITY STUDY DATA
1.	Reference of previous app stability study data of the			

2.	**	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 275 th 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	
10	used for manufacturing of Injection and capsule is used.	
10	Submit drug excipient compatibility studies, since your	
	qualitative composition is different from that of	
10	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	
12	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.	

on: Registration Board deferred the case for submission of reply to the above cited shortcoming Name, address of Applicant / Marketing M/s Curatech Pharma pvt Ltd 35-Km, Mul-		
Authorization Holder	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: Cephradine250mg	
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.	

T	A TO BE PROVIDED An oroval of applications with	LONG WITH STABII	LITY STUDY DATA	
No. of Batches		03		
Date of Initiation	26-07-2021	26-07-2021 26-07-2021		
Manufacturing Date	07-2021	07-2021	07-2021	
Batch Size 600 bottles		600 bottles	600 bottles	
Batch No.	TR-CEP-12	TR-CEP-13	TR-CEP-14	
Frequency	Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mon			
Time Period	Real time: 6 months Accelerated: 6 months			
Stability Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Description of Pack (Container closure system)	Glass bottle			
API Lot No.	00203/163/2020	t 14001 Buksiiwala, 34 IX	m, r crozepur Roda, Editore.	
Manufacturer of API			m, Ferozepur Road, Lahore.	
product	STABILITY ST	substance and the drug product. LIDY DATA		
Dissolution Profile Analytical method v	Analytical method validation/verification of		Firm has submitted verification studies of the drug	
Diameter died Ferrie	1 1. C	specifications, reference standard or materials container closure system and stability.		
Wodale III Drug I rodu	Module-III Drug Product:		its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of	
(Conditions & duration Module-III Drug Produ	*		er refrigerated conditions. nta of drug product including	
Stability Studies of Dru		Firm has submitted sta	ability study data of 3 batches	
Module-III Drug Substa	ance:	data related to nome properties, solubil manufacturers, descrip and controls, impuriti procedures and its va justification of specif	tailed data for drug substance enclature, structure, general ities, physical form, tion of manufacturing process les, specifications, analytical alidation, batch analysis and fication, reference standard, m and stability studies of drug	
		its validation, batch a specification, reference system and stability studing product.	ons, analytical procedures and analysis and justification of e standard, container closure tudies of drug substance and	

2.	**	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	
6.	3.2.S.4.4.	
0.	Specify whether the drug substance used is cephradine or cephradine monohydrate	
7.	Justify how cephradine plain is used to manufacture	
7.	cephradine suspension instead of using cephradine	
	micronized.	
8.	Submit COA of cephalexin reference standard which is also	
0.	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	
10	of each time point and batch.	
13	Submit BMR of three stability batches.	

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	Road, Lahore M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore ⊠ Manufacturer □ Importer □ Is involved in none of the above (contract giver) Firm has submitted copy of GMP certificate issued on the basis of inspection dated 19-02-2020 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. □ New Drug Product (NDP) ⊠ Generic Drug Product (GDP) □ Domestic sale □ Export sale ⊠ Domestic and Export sales Dy. No. 2552: 26-01-2023 PKR 30,000/-: 28-11-2022 VELOSEM 250mg Capsule Each Capsule Contains: Cephradine250mg Hard gelatin capsule Cephalosporin Antibiotic USP As per SRO Cephradine capsule (MHRA Approved) Velosef capsule by GSK Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore. 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, reference standard, container closure	
	Intended use of pharmaceutical product	☐ Export sale	
	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		
	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)	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	

			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 (Conditions & duration			ability study data of 3 batches er 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 Equiva Dissolution Profile	lence and Comparativ	е		
	Analytical method v product	alidation/verification o		Firm has submitted verification studies of the drug substance and the drug product.	
	•	STABILITY S	TUDY DATA	UDY DATA	
Manu	afacturer of API	Pharmagen Limited. K	ot Nabi Bukshwala, 34 K	Km, Ferozepur Road, Lahore.	
API I	Lot No.				
	ription of Pack tainer closure system)	Alu-alu blister			
Stabi	lity Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	iency	Accelerated: 0, 3, 6 (Mo	1.5		
Batch	ı No.	TR-CEP-01	TR-CEP-02	TR-CEP-03	
Batch	n Size	1500 capsule	1500 capsule	1500 capsule	
Manu	ufacturing Date	06-2021	06-2021	06-2021	
Date	of Initiation	02-07-2021	02-07-2021	02-07-2021	
No. c	of Batches		03	03	
	DOCUMENTS / DATA	A TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA	
1.	Reference of previous app stability study data of the	* *			
2.		/GMP certificate of API Firm has submitted copy of GMP certificate Pharmagen issued on the basis of inspection dated 2 of 2006-2020.			
3.	Documents for the procurement of API with approval from DRAP (in case of import).				

ation Holder	Roud, Editore
dress of Applicant / Marketing	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore
	mission of reply to the above cited shortcomings.
BMR of three stability batches.	
time point and batch.	
sequence with tagging to differentiate b	
ent. Moreover, the stability data shall be	
the 6 points checklist specified in the C	
stability study data of drug product in se	ction 3.2.P.8
why your analytical procedure is different raph.	nt from USP
report of pharmaceutical equivalence as .	well as CDP
t.	
tive composition is different from that	of reference
drug excipient compatibility studies,	since your
nufacturing of Injection and capsule is us	
how same stability study data of cephrad	ine API used
d in the analysis of drug substance.	which is also
COA of cephalexin reference standard v	
how cephradine plain is used to dine capsule instead of using cephradine	
dine monohydrate	manufactura
whether the drug substance used is co	ephradine or
ace as well as drug product manufacture4.	
t development and stability studies from	
COA of relevant batch of drug substa	
ent approved by Registration Board	
data in section 3.2.S.4.3 as per the	ne guidance
3.2.S.4.1 and 3.2.S.4.2.	
ubstance from the drug product man	
specifications as well as analytical me	ethod of the
as OSI monograph. Justification is req	uned in this
as USP monograph. Justification is req	
ethod of analysis of the drug substance of d submitted in section 3.2.S.4.2 is differ	
ce product along with submission of req	
label claim of applied product in li	
omings communicated	Response by the firm
<u> </u>	
EC:	
celerated)	
Digital data logger for temperature and nonitoring of stability chambers (real	
eports on product testing	
Record of HPLC software 21CFR &	
•	
pective documents like chromatograms,	
ability batches will be supported by	
pective do	

☑ Manufacturer☐ Importer

Status of the applicant

	☐ 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: Cephradine500mg
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.

			Firm has submitted stability study data of 3 batches of drug substance as per refrigerated conditions.	
Module-III Drug Produc	Module-III Drug Product:		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
Pharmaceutical Equiva Dissolution Profile	lence and Comparative			
Analytical method viproduct	alidation/verification of	Firm has submitted v substance and the drug	erification studies of the drug g product.	
	STABILITY ST	UDY DATA		
Manufacturer of API	Pharmagen Limited. Ko	t Nabi Bukshwala, 34 k	Km, Ferozepur Road, Lahore.	
API Lot No.				
Description of Pack (Container closure system)	Alu-alu blister			
Stability Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0, 3, 6 (MorReal Time: 0, 3, 6 (Mor			
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	A TO BE PROVIDED A	LONG WITH STABI	LITY STUDY DATA	
1. Reference of previous appropriate stability study data of the factors.				
manufacturer issued by	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).			
attested respective docume	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 Haudit trail reports on produ				
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (rea			
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.	

140.	Name, address of Applicant / Mar keting Authorization Holder	M/s Curatech Pharma pvt Ltd 35-Km, Multan Road, Lahore	
		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.

			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
	Pharmaceutical Equiva Dissolution Profile	lence and Comparativ	e		
	Analytical method va product	alidation/verification o	analytical method for Firm has submitted	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 S	TUDY DATA		
Man	ufacturer of API	Danuka Lboratories Mohammedpur Gurga	Limited , 7Km Ol on , Haryana	d Manesar Road, Village	
API	Lot No.				
	ription of Pack tainer closure system)	Glass vials			
Stabi	lity Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	uency	Accelerated: 0, 3, 6 (Mo			
Batcl	n No.	TR-CEP-78	TR-CEP-79	TR-CEP-80	
Batcl	n Size	875 Bottles	875 Bottles	875 Bottles	
Man	ufacturing Date	09-2021	09-2021	09-2021	
Date	of Initiation	21-09-2021	21-09-2021	21-09-2021	
No. o	of Batches		03		
	DOCUMENTS / DATA	TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA	
1.	Reference of previous appr stability study data of the f		h Not submitted		
2.	Approval of API/ DML/GMP certificate of API I manufacturer issued by concerned regulatory by				
3.		uments for the procurement of API with oval from DRAP (in case of import).			
4.	Data of stability batches attested respective docume Raw data sheets, COA, sur	ents like chromatograms	tograms,		
5.	Compliance Record of HI audit trail reports on produ		Not submitted		
6.	Record of Digital data log humidity monitoring of time and accelerated)				
Eval	uation by PEC:				

r. No	Shortcomings communicated	Response by the firm
	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."	
	Submit verification studies of analytical method of drug	
	substance performed by drug product manufacturer.	
	Submit COA of relevant batch of API from API	
	manufacturer as well as from drug product manufacturer.	
	Submit COA of reference standard used in the analysis of	
	drug substance.	
	Submit evidence of requisite storage facility to store	
	cephradine at refrigerated conditions within the raw	
	material warehouse.	
	Submit drug-excipient compatibility studies since your	
	formulation is qualitatively different from reference	
	product.	
•	Submit pharmaceutical equivalence in section 3.2.P.2.2.1	
•	Submit data of compatibility of the drug product in section 3.2.P.2.5.	
	Submit microbiological attributes in section 3.2.P.2.6.	
	Submit preservative effectiveness studies.	
0.	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.	
1.	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.	
2.	Submit BMR of three stability batches.	

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-Arginine250mg
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 Ferozepur Road, Lahore.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS template. Firm has summarized information rel to nomenclature, structure, general proper solubilities, physical form, manufacture description of manufacturing process and containing impurities, specifications, analytical procedures its validation, batch analysis and justification specification, reference standard, container closystem and stability studies of drug substance drug product.
Module-III Drug Substance:	Firm has submitted detailed data for both of substance data related to nomenclature, struct general properties, solubilities, physical for manufacturers, description of manufacturing product and controls, impurities, specifications, analytic procedures and its validation, batch analysis justification of specification, reference stand container closure system and stability studies of of substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 bate of drug substance as per refrigerated conditions.
Module-III Drug Product:	Firm has submitted data of drug product includits description, composition, pharmaceut development, manufacture, manufacturing product and process control, process validation protoc control of excipients, control of drug product specifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or matericontainer closure system and stability.

	-				1		
	D	issolution Profile					
		nalytical method v oduct	ralidation/verification	of	analy Firm	ytical method for has submitted	I report of verification of the drug substance. I report of verification of the drug product.
			STABILITY	ST	UDY	DATA	
Man	ufact	urer of API	Pharmagen Limited	Kot	Nabi	Bukshwala, 34 K	Em Ferozepur Road, Lahore.
API	Lot N	Jo.					
	•	on of Pack or closure system)	Glass vials				
Stab	ility S	Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm$				
Time	e Peri	od	Real time: 6 months Accelerated: 6 month	hs			
Freq	uenc	у	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N	•			
Batc	h No						
Batc	h Siz	e					
Man	ufact	uring Date					
Date	of In	nitiation					
No.	of Ba	tches		1		03	
	D	OCUMENTS / DATA	A TO BE PROVIDEI) A	LONG	G WITH STABI	LITY STUDY DATA
1.		erence of previous appaility study data of the	roval of applications w	ith	Not s	ubmitted	
2.	2. Approval of API/ DML/		/GMP certificate of API Firm has submitted copy of GMP certification concerned regulatory Pharmagen issued on the basis of inspection 06-2020.		* •		
3.	Doc	numents for the pro roval from DRAP (in c	curement of API w	with Not submitted			
4.	4. Data of stability batches attested respective docume			ns,	Subn	nitted	
5.	Con		PLC software 21CFR		Not s	ubmitted	
6.				Subn	iitted		
Eval	luatio	on by PEC:					
Sr. 1.	No	Submit label claim of	nunicated of applied product in li	ino	with	Response by th	e firm
1.			of applied product in h				
		requiste fee.					
2.			ertificate / inspection r	repo	rt of		
3.		the srug product man	nutacturer. on 3.2.S.4.1 and 3.2.S.4	2 a	s per		
] .			nent approved by Reg				
Board which s		Board which specifi	ies that "Copies of th	he I	Orug		
		L substance specificati	ions and analytical pro	sced	ures		

substance specifications and analytical procedures

	yand for mouting testing of the Days substance	
	used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug	
	substance & Drug Product manufacturer is	
4	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	
10	document.	
10.	Submit pharmaceutical equivalence in section	
11	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	
10	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	
4.4	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	n: Registration Board deferred the case for submissi	on 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
D. N. 114 C. 1	
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-Arginine500mg
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.

	DI	hamma aquti aql Equiyy	alance and Commenti				
		issolution Profile	alence and Comparati	ve			
	Analytical method validation/verification of product			anal Firm	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		
Man	ufact	urer of API	Pharmagen Limited k	Kot Nabi	Bukshwala, 34 K	m Ferozepur Road, Lahore.	
API	Lot N	No.					
		on of Pack er closure system)	Glass vials				
Stab	ility S	Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$				
Time	e Peri	od	Real time: 6 months Accelerated: 6 month	s			
Freq	uency	y	Accelerated: 0, 3, 6 (I Real Time: 0, 3, 6 (M	,			
Batc	h No	•	TR-CEP-07	Т	R-CEP-08	TR-CEP-09	
Batc	h Siz	e	1100 vials		1100 vials	1100 vials	
Man	ufact	uring Date	07-2021		07-2021	07-2021	
Date	of In	nitiation	09-07-2021	C	9-07-2021	09-07-2021	
No.	of Ba	tches			03		
	D	OCUMENTS / DAT	A TO BE PROVIDED	ALON	G WITH STABI	LITY STUDY DATA	
1.		erence of previous app ility study data of the	proval of applications wi firm (if any)	th Not	submitted		
2.	man		y concerned regulato	ry Phar	Firm has submitted copy of GMP certificate of Pharmagen issued on the basis of inspection dated 22 06-2020.		
3.		numents for the proposed from DRAP (in	ocurement of API wi case of import).	th Not	submitted		
4.	atte	sted respective docum	es will be supported la nents like chromatogram ummary data sheets etc.	-	nitted		
5.		npliance Record of H it trail reports on prod	IPLC software 21CFR uct testing	& Not	submitted		
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)				nitted		
Eval	luatio	on by PEC:					
Sr	No	Shortcomings com	municated		Response by th	o firm	
1.	110	Ü	of applied product in lin	ne with	Kesponse by th	e m m	
the			act along with submiss	sion of			
2.		requiste fee. Submit valid GMP	certificate / inspection re	eport of			
² .		the srug product ma	_	port or			
3.		Submit data in section	on 3.2.S.4.1 and 3.2.S.4.				
			ment approved by Registration fies that "Copies of the Drug				
<u> </u>		Board which specif	nes mai Copies of th	Drug			

	substance specifications and analytical proced	
	used for routine testing of the Drug subst	
	/Active Pharmaceutical Ingredient by both I	
	substance & Drug Product manufacturer required."	r 18
4.	Specify whether the drug substance is cephradia	na or
4.	cephradine monohydrate.	lie of
5.	Submit verification studies of analytical metho	od of
٥.	drug substance performed by drug pro	
	manufacturer.	
6.	Submit COA of relevant batch of API from	API
	manufacturer as well as from drug pro	
	manufacturer.	
7.	Submit COA of reference standard used in	the
	analysis of drug substance.	
8.	Submit evidence of requisite storage facilit	
	store cephradine at refrigerated conditions w	ithin
	the raw material warehouse.	
9.	Submit data in section 3.2.P.1 as per CTD guid	ance
	document.	
10.	Submit pharmaceutical equivalence in sec	ction
4.4	3.2.P.2.2.1	
11.	Submit data of compatibility of the drug produ	ct in
12.	section 3.2.P.2.5.	ation .
12.	Submit microbiological attributes in sec 3.2.P.2.6.	etion
13.	Submit proper fill weight per vial for the app	plied
13.	product and also complete calculation how that	
	weight is equivalent to the content of cephradia	
	per the label claim.	ic as
14.	Submit stability study data of drug produc	et in
,	section 3.2.P.8 as per the 6 points chec	
	specified in the CTD guidance docum	
	Moreover, the stability data shall be submitted	
	proper sequence with tagging to differen	tiate
	between data of each time point and batch.	
15.	Submit BMR of three stability batches.	
Decisi	ion: Registration Board deferred the case for sub	mission of reply to the above cited shortcomings.
143.	Name, address of Applicant / Mar keting	M/s Curatech Pharma pvt Ltd 35-Km, Multan
	Authorization Holder	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 leter of grant of
	Evidence of approval of manufacturing facility	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-Arginine1g
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

					ence standard or materials, em and stability.	
	Analytical method viproduct	alidation/verification	anal Firn	ytical method for has submitted	I report of verification of the drug substance. I report of verification of the drug product.	
	•	STABILITY	STUDY	DATA		
Mar	nufacturer of API	Pharmagen Limited I	Kot Nabi	Bukshwala, 34 K	m Ferozepur Road, Lahore.	
API	Lot No.					
	cription of Pack ntainer closure system)	Glass vials				
Stab	pility Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$				
Tim	ne Period	Real time: 6 months Accelerated: 6 month	ns			
Free	quency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (Mark)				
Bato	ch No.	TR-CEP-10	T	R-CEP-11	TR-CEP-12	
Bato	ch Size	1100 vials	1	100 vials	1100 vials	
Mar	nufacturing Date	07-2021		07-2021	07-2021	
Date	e of Initiation	09-07-2021	0	9-07-2021	09-07-2021	
No.	of Batches			03		
	DOCUMENTS / DATA	TO BE PROVIDED	ALON	G WITH STABI	LITY STUDY DATA	
1.	Reference of previous appropriate stability study data of the		ith Not s	submitted		
2.		concerned regulate		magen issued on tl	copy of GMP certificate of the basis of inspection dated 22-	
3.	Documents for the pro- approval from DRAP (in c		ith Not s	submitted		
4.	Data of stability batches attested respective docume Raw data sheets, COA, sur	ents like chromatogran	ns,	nitted		
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)				nitted		
Eva	luation by PEC:					
C.	No. Chantagnings comm			Dogwongo by 4h	o 6°	
1.	the reference produ	of applied product in li ct along with submis		Response by th	e nrm	
2.	requiste fee.2. Submit valid GMP certificate / inspection report 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.	
	•	

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	
	GMP status of the firm	Firm has been granted new license dated 11 th November 2021 for following sections:

Evidence of approval of manufacturing facility	 Tablet (General) Capsule (General) Cream /ointment section (General) Tablet (Hormone) Dry Powder Suspension (General) Firm has been granted new license dated 11th
Evidence of approval of manufacturing facility	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 hemihydrate250 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 syste substance.	em and stability studies of drug	
	•		Firm has submitted sta of drug substance	ability study data of 3 batches	
	Pharmaceutical Equivalence and Comparative Dissolution Profile		its description, co development, manufa and process control, control of excipients specifications, analyti analytical procedures, specifications, refere	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
			equivalence for the q against Leflox Tablet	results of pharmaceutical quality tests for their product of Getz. DP studies in 3 medium against	
	Analytical method v product	alidation/verification o	analytical method for	report of verification of	
	-	STABILITY S	TUDY DATA		
Manı			armaceutical Co., Ltd Coa y,Zhejiang, China	astel Industrial City, Pubagang	
API	Lot No.	DC-004-2205017			
	ription of Pack tainer closure system)	Alu-Alu Blister			
Stabi	lity Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time	Period	Real time: 6 months Accelerated: 6 months	3		
Frequ	uency	Accelerated: 0, 3, 6 (Me Real Time: 0, 3, 6 (Me	The state of the s		
Batcl	n No.	T-01	T-02	T-03	
Batcl	n Size	1500 Tablet	1500 Tablet	1500 Tablet	
Manı	ufacturing Date	03-2023	03-2023	03-2023	
Date	of Initiation	17-03-2023	17-03-2023	17-03-2023	
No. o	of Batches		03		
	DOCUMENTS / DATA	A TO BE PROVIDED	ALONG WITH STABII	LITY STUDY DATA	
1.	Reference of previous app stability study data of the		h New License		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			ate on the basis of evaluation 122 is submitted.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).			ecifying 300Kg levofloxacin	

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 & Firm has submitted that their HPLC system i audit trail reports on product testing CFR compliant.	
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Eval	uation by PEC:	
Sr.		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.	
Decis	sion: Registration Board deferred the case for sub	mission of reply to the above cited shortcomings.
145.	Name, address of Applicant / Marketing	M/s Pasteur & Fleming Pharmaceuticals Plot #
	Authorization Holder	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 11 th 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 11 th 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 hemihydrate500 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	or the drug product.	
	STABILITY STUDY DATA					
Manufacturer of API Zhejiang			Zhejiang East-Asia Pharmaceutical Co., Ltd Coastel Industrial City, Pubagang Town, Sanmen County, Zhejiang, China			
API	Lot N	No.	DC-004-2205017			
		on of Pack or closure system)	Alu-Alu Blister			
Stab	ility S	Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Tim	e Peri	od	Real time: 6 months Accelerated: 6 month	s		
Freq	uenc	у	Accelerated: 0, 3, 6 (Name of Name of			
Bato	h No		T-04	T-05	T-06	
Bato	h Siz	e	1500 Tablet	1500 Tablet	1500 Tablet	
Man	ufact	uring Date	03-2023	03-2023	03-2023	
Date	of In	nitiation	17-03-2023	17-03-2023	17-03-2023	
No.	of Ba	tches		03		
	D	OCUMENTS / DATA	TO BE PROVIDED	ALONG WITH STAB	SILITY STUDY DATA	
1.		erence of previous apprility study data of the	roval of applications wi Firm (if any)	th New License		
2.	2. Approval of API/ DML/GMP certificate of A manufacturer issued by concerned regulate authority of country of origin.		concerned regulator	_{rv} Copy of GMP Certif		
3.		numents for the pro roval from DRAP (in c		dated 25-10-2022 s	Firm has submitted copy of clearance certificate dated 25-10-2022 specifying 300Kg levofloxacin dated by legacy pharma.	
4.	atte	sted respective docume	s will be supported beents like chromatogram mmary data sheets etc.	s, batches along with cl	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 to CFR compliant.	•		
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (reatime and accelerated)			record of digital data logger for idity monitoring of real time and chambers.		
Eva	Evaluation by PEC:					
C	N1.	Choutes		Dognamas 1 41 6*		
1.	No	Shortcomings Submit valid GM	P certificate of AF	Response by the fir	m	
		manufacturer.				
2.			om Legacy Pharma sind ments of Legacy pharm			
		has been submitted.	ments of Legacy pharm	a		
3.		Submit complete including HPLC chrodata and related and	stability study date omatograms, dissolutionalytical record since number in module 3.	n		

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 11 th 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 11 th 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	

		specification, reference	analysis and justification of ce standard, container closure studies of drug substance and	
Module-III Drug Substa			detailed data for both drug d to nomenclature, structure, solubilities, physical form, ption of manufacturing process ties, specifications, analytical ralidation, batch analysis and ification, reference standard, em and stability studies of drug	
Stability Studies of Drug (Conditions & duration of		Firm has submitted st of drug substance	ability study data of 3 batches	
Module-III Drug Product:		its description, c development, manufa and process control, control of excipient specifications, analyta analytical procedures,	lata of drug product including omposition, pharmaceutical acture, manufacturing process process validation protocols, s, control of drug product, ical procedures, validation of batch analysis, justification of ence standard or materials, em and stability.	
Pharmaceutical Equival Dissolution Profile	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 va	alidation/verification o	analytical method for Firm has submitted	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 S	TUDY 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 : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No.	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.	1			
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)				
Eval	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

Case No. 02 Registration applications of CTD cases

submitted in the registration application.

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	

Pharmaceutical form of applied drug Pharmaceutical form of applied drug Pharmaceutical form of applied drug Plain from both sides Reference to Finished product specifications Reference to Finished product specifications Proposed Pack size Proposed Pack size Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Na Name and address of API manufacturer. CTX Lifesciences Pvt Ltd. Block No. 251-2: Sachin Magdalla Road G.I.D.C. Sachin Surat Guj India Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-1 template. Firm has summarized information relat to nomenclature, structure, general propertis solubilities, physical form, manufacture description of manufacturing process and control impurities, specification, reference standard, container closs system and stability studies of drug substance a drug product. Module-III Drug Substance: Firm has submitted detailed drug substance and related to nomenclature, structure, general properties, solubilities, physical for manufacturing process and controls, impurities, specification analytical procedures and its validation, batch analysis and justification of manufacturing process and controls, impurities, specification analytical procedures and its validation bata analysis and 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 includi its description, composition, pharmaceutic development, manufacture, manufacturing proceading process control, process validation protoco control of excipients, control of drug product procedures, batch analysis, justification specifications, analytical procedures, batch analysis, justification specifications, analytical procedures, batch analysis, justification specifications, analytical procedures validation analytical procedures standard or materia cont		☐ Domestic and Export sales
The proposed proprietary name / brand name Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Pharmacotherapeutic Group of (API) Pharmacotherapeutic Group of (API) Pharmaceutical form of applied drug Pharmaceutical form of applied drug Pharmaceutical form of applied drug Proposed Pack size Proposed Pack size Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Sachin Magdalla Road G.I.D.C, Sachin Surat Guj India Module-II (Quality Overall Summary) Module-III (Quality Overall Summary) Module-III Drug Substance: Module-III Drug Substance: Module-III Drug Substance: Firm has submitted detailed drug substance drelated to nomenclature, structure, general properties, solubilities, physical for manufacturing process and controls, impurities, specification, reference standard, container closs 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 includi its description, composition, pharmaceutic development, manufacturic procedures, validation analytical procedures, subtleant analysis, justification analytical procedures, subtleant analysis, justification analytical procedures, validation process and process control, process validation process and process validation process and process control, process validation process and procedures, validation process and process control, process validation process and process control, process validation process and process process, stach analysis, justification analytical procedures, validation analytical procedures, validation analytical procedures, validation analytical procedures, validation process control of excipients, control of drug production a	Dy. No. and date of submission	Dy. No 22884 dated 12-08-2022
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit medoxomil	Details of fee submitted	PKR 75,000/- Dated 19-04-2022
Pharmaceutical ingredient (API) per unit Azilsartan medoxomil potassium eq to Azilsartan medoxomil potassium eq to Azilsartan medoxomil	The proposed proprietary name / brand name	XYSARTAN 40mg Tablet
Pharmaceutical form of applied drug Yellow colored uncoated round shape core tab plain from both sides Manufacturer's Proposed Pack size Proposed unit price The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. CTX Lifesciences Pvt Ltd. Block No. 251-25 Sachin Magdalla Road G.I.D.C, Sachin Surat Guj India Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-1 template. Firm has summarized information relat to nomenclature, structure, general propertic solubilities, physical form, manufacture description of manufacturing process and control impurities, specification, reference standard, container closs system and stability studies of drug substance a drug product. Module-III Drug Substance: Firm has submitted detailed drug substance delated to nomenclature, structure, gene properties, solubilities, physical form manufacturing process and control impurities, specification, reference standard, container closs system and stability studies of drug substance a drug product. Firm has submitted detailed drug substance delated to nomenclature, structure, gene properties, solubilities, mphysical form manufacturing process and controls, impurities, specification analytical procedures and its validation, bat analysis and 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 includi its description, composition, pharmaceutic development, manufacture; proceading process control, process validation analytical procedures, batch analysis, justification specifications, analytical procedures, validation analytical proce		Azilsartan medoxomil potassium eq to Azilsartan
Reference to Finished product specifications Reference to Finished product specifications Manufacturer's 10's, 20's, 30's, 28's, 14's As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. CTX Lifesciences Pvt Ltd. Block No. 251-2: Sachin Magdalla Road G.I.D.C., Sachin Surat Guj India Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-1 template. Firm has summarized information relat to nomenclature, structure, general propertic solubilities, physical form, manufacture description of manufacturing process and control impurities, specification, analytical procedures a its validation, batch analysis and justification specification, reference standard, container clost system and stability studies of drug substance a drug product. Firm has submitted detailed drug substance a drug product. Firm has submitted detailed drug substance a drug product. Firm has submitted detailed drug substance a related to nomenclature, structure, gene properties, solubilities, physical for manufacturers, description of manufacturin process and controls, impurities, specification analytical procedures and its validation, bat analysis and 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 includitits description, composition, pharmaceutic development, manufacture, manufacturing procedures and process control, process validation protoco control of excipients, control of drug produs specifications, analytical procedures, validation analytical procedures, validation analytical procedures, validation analytical procedures, validation specifications, reference standard or materia container closure system and stability.	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blocker
Proposed Pack size Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Na Name and address of API manufacturer. Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-I template. Firm has submitted QOS as per WHO QOS-I template. Firm has submitted process and control impurities, specification, analytical procedures a its validation, batch analysis and justification of manufacturer, general properties, system and stability studies of drug substance a drug product. Firm has submitted detailed drug substance analytical procedures and its validation, batch analysis, specification, reference standard, container closs system and stabilities, physical for manufacturer, structure, gene properties, solubilities, physical for manufacturers, solubilities, physical for manufacturers, description of manufacturers, solubilities, physical for manufacturers, description of manufacturers, specification analytical procedures and its validation, bat analysis and justification of specification, referent 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 includi its description, composition, pharmaceutic development, manufacture, manufacturing proceand process control, process validation protect on the process control, process validation protect on the process control of excipients, control of drug product specifications, analytical procedures, batch analysis, justification specifications, reference standard or materia container closure system and stability. Pharmaceutical Equivalence and Comparative Firm has submitted pharmaceutical equivalence	Pharmaceutical form of applied drug	Yellow colored uncoated round shape core table plain from both sides
Proposed unit price The status in reference regulatory authorities For generic drugs (me-too status) Na Name and address of API manufacturer. CTX Lifesciences Pvt Ltd. Block No. 251-25 Sachin Magdalla Road G.I.D.C, Sachin Surat Guj India Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-I template. Firm has summarized information relat to nomenclature, structure, general propertis solubilities, physical form, manufacture description of manufacturing process and control impurities, specifications, analytical procedures a its validation, batch analysis and justification specification, reference standard, container closs system and stability studies of drug substance a drug product. Module-III Drug Substance: Firm has submitted detailed drug substance drelated to nomenclature, structure, gene properties, solubilities, physical for manufacturers, description of manufacturi process and controls, impurities, specification analysis and justification of specification, bat analysis and justification of specification, bat analysis and justification of specification, referen standard, container closure system and stabil 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 includi its description, composition, pharmaceutic development, manufacture, manufacturing proce and process control, process validation protoco control of excipients, control of drug produs specifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or materia container closure system and stability. Pharmaceutical Equivalence and Comparative Firm has submitted pharmaceutical equivalence	Reference to Finished product specifications	Manufacturer's
The status in reference regulatory authorities For generic drugs (me-too status) Na Name and address of API manufacturer. CTX Lifesciences Pvt Ltd. Block No. 251-2: Sachin Magdalla Road G.I.D.C, Sachin Surat Guj India Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-1 template. Firm has summarized information relat to nomenclature, structure, general propertical solubilities, physical form, manufacture description of manufacturing process and control impurities, specifications, analytical procedures a its validation, batch analysis and justification specification, reference standard, container clost system and stability studies of drug substance a drug product. Module-III Drug Substance: Firm has submitted detailed drug substance description of manufacturing process and controls, impurities, specification analytical procedures and its validation, bat analysis and justification of pecification, feference standard, container closure system and stabil 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 includi its description, composition, pharmaceutic development, manufacture, manufacturing proce and process control, process validation protoco control of excipients, control of drug produ specifications, analytical procedures, batch analysis, justification analytical procedures, batch analysis, justification specifications, reference standard or materia container closure system and stability. Pharmaceutical Equivalence and Comparative Firm has submitted pharmaceutical equivalence	Proposed Pack size	10's, 20's, 30's, 28's, 14's
For generic drugs (me-too status) Name and address of API manufacturer. CTX Lifesciences Pvt Ltd. Block No. 251-2: Sachin Magdalla Road G.I.D.C, Sachin Surat Guj India Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-t template. Firm has summarized information relat to nomenclature, structure, general propertical solubilities, physical form, manufacture description of manufacturing process and control impurities, specifications, analytical procedures a its validation, batch analysis and justification specification, reference standard, container clost system and stability studies of drug substance a drug product. Module-III Drug Substance: Firm has submitted detailed drug substance description of manufacture, gene properties, solubilities, physical for manufacturers, description of manufacturing process and controls, impurities, specification analytical procedures and its validation, bat analysis and justification of specification, reference standard, container closure system and stabil 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 includi its description, composition, pharmaceutic development, manufacture, manufacturing proce and process control, process validation protoco control of excipients, control of drug produs procifications, analytical procedures, batch analysis, justification specifications, reference standard or materia container closure system and stability. Pharmaceutical Equivalence and Comparative Firm has submitted pharmaceutical equivalence	Proposed unit price	As per SRO
Name and address of API manufacturer. CTX Lifesciences Pvt Ltd. Block No. 251-25 Sachin Magdalla Road G.I.D.C, Sachin Surat Guj India Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-1 template. Firm has summarized information relat to nomenclature, structure, general properties olubilities, physical form, manufacture description of manufacturing process and control impurities, specifications, analytical procedures a its validation, batch analysis and justification specification, reference standard, container closs system and stability studies of drug substance a drug product. Module-III Drug Substance: Firm has submitted detailed drug substance derelated to nomenclature, structure, gene properties, solubilities, physical for manufacturers, description of manufacturin process and controls, impurities, specification, analytical procedures and its validation, bat analysis and justification of specification, bat analysis and justification of specification, referent standard, container closure system and 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, pharmaceutic development, manufacture, manufacturing procest and process control, process validation protoco control of excipients, control of drug product specifications, reference standard or materia container closure system and stability. Pharmaceutical Equivalence and Comparative Firm has submitted pharmaceutical equivalence	The status in reference regulatory authorities	Edarbi Tablet (USFDA Approved)
Sachin Magdalla Road G.I.D.C, Sachin Surat Guj India Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-I template. Firm has summarized information relat to nomenclature, structure, general propertis solubilities, physical form, manufacture description of manufacturing process and control impurities, specifications, analytical procedures a its validation, batch analysis and justification specification, reference standard, container closs system and stability studies of drug substance a drug product. Module-III Drug Substance: Module-III Drug Substance: Firm has submitted detailed drug substance drelated to nomenclature, structure, gene properties, solubilities, physical for manufacturers, description of manufacturi process and controls, impurities, specification analytical procedures and its validation, bat analysis and justification of specification, referen standard, container closure system and stabil 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 includi its description, composition, pharmaceutic development, manufacture, manufacturing proce and process control, process validation protoco control of excipients, control of drug produ specifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or materia container closure system and stability. Pharmaceutical Equivalence and Comparative	For generic drugs (me-too status)	NA
template. Firm has summarized information relat to nomenclature, structure, general propertical solubilities, physical form, manufacture description of manufacturing process and control impurities, specifications, analytical procedures a its validation, batch analysis and justification specification, reference standard, container closs system and stability studies of drug substance and drug product. Module-III Drug Substance: Firm has submitted detailed drug substance destricted to nomenclature, structure, gene properties, solubilities, physical for manufacturers, description of manufacturing process and controls, impurities, specification analytical procedures and its validation, bat analysis and justification of specification, reference standard, container closure system and stabil 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, pharmaceutic development, manufacture, manufacturing process control, process validation protocococometrol of excipients, control of drug product specifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or materia container closure system and stability. Pharmaceutical Equivalence and Comparative	Name and address of API manufacturer.	CTX Lifesciences Pvt Ltd. Block No. 251-252 Sachin Magdalla Road G.I.D.C, Sachin Surat Gujra India
related to nomenclature, structure, gene properties, solubilities, physical for manufacturers, description of manufacturi process and controls, impurities, specification analytical procedures and its validation, bat analysis and justification of specification, referent standard, container closure system and stabil 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, pharmaceutic development, manufacture, manufacturing process and process control, process validation protocotocontrol of excipients, control of drug produst specifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or materiate container closure system and stability. Pharmaceutical Equivalence and Comparative Firm has submitted pharmaceutical equivalence	Module-II (Quality Overall Summary)	template. Firm has summarized information relate to nomenclature, structure, general properties solubilities, physical form, manufacturers description of manufacturing process and controls impurities, specifications, analytical procedures an its validation, batch analysis and justification of specification, reference standard, container closur system and stability studies of drug substance and
(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 protocol control of excipients, control of drug products specifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or material container closure system and stability. Pharmaceutical Equivalence and Comparative Firm has submitted pharmaceutical equivalence		properties, solubilities, physical form manufacturers, description of manufacturin process and controls, impurities, specification analytical procedures and its validation, bate analysis and justification of specification, reference standard, container closure system and stability
its description, composition, pharmaceutic development, manufacture, manufacturing process and process control, process validation protoco control of excipients, control of drug produ specifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or materia container closure system and stability. Pharmaceutical Equivalence and Comparative Firm has submitted pharmaceutical equivalence		
	Module-III Drug Product:	development, manufacture, manufacturing process and process control, process validation protocol control of excipients, control of drug product specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or material
		Firm has submitted pharmaceutical equivalence their product against the innovator's product Edar

			40mg Tablet Firm has submitted CDP against the innovator's pro in 3 dissolution medias.	
	Analytical method v	validation/verification of	Firm has submitted anal study reports for drug su product.	
		STABILITY ST	UDY DATA	
Man	ufacturer of API	CTX Lifesciences Pvt G.I.D.C, Sachin Surat C	Ltd. Block No. 251-252, Bujrat India	Sachin Magdalla Road
API	Lot No.	21AK000004		
	cription of Pack ntainer closure system)	Alu-alu Blister		
Stab	ility Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time	e Period	Real time: 6 months Accelerated: 6 months		
Freq	uency	Accelerated: 0, 3, 6 (Mor Real Time: 0, 3, 6 (Mor		
Batc	h No.	RD/PR21-091/T1/S1	RD/PR21-091/T1/S2	RD/PR21-091/T1/S2
Batc	h Size	2000 Tablet	2000 Tablet	2000 Tablet
Man	ufacturing 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	A TO BE PROVIDED A	LONG WITH STABILITY	Y STUDY DATA
1.	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.			021 issued by Food and on Gujrat State India. The license to manufacture
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 analytic testing.	cal record for product
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Firm has submitted certification for the HPLC system	ate of 21 CFR compliance
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			nonitoring of real time and
Eval	uation by PEC:			
<u>C</u>	No Charter.		Dogmo k 41 - 6*	
Sr. 1.	No Shortcomings common Submit data in section	nunicated on 3.2.S.4.1 and 3.2.S.4.2	Response by the firm	
1.	as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications			

	and analytical procedures used for routine	
	testing of the Drug substance /Active	
Pharmaceutical Ingredient by both Drug		
	substance & Drug Product manufacturer is	
	required."	
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.	
Decisi	on: Registration Board deferred the case for sub	nission of reply to the above cited shortcomings.
148.	Name, address of Applicant / Marketing	M/s Novamed Pharmaceuticals (Pvt) Ltd 28-Km,
140.	Authorization Holder	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	M Novy Deng Broduct (NDB)
	Samus of application	New Drug Product (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 Compa Dissolution Profile		parative	Firm has submitted pharm their product against the in 80mg Tablet Firm has submitted CDP against the innovator's proin 3 dissolution medias.	nnovator's product Edarbi results of their product
	Analytical method v product	alidation/verificati	ion of	Firm has submitted analystudy reports for drug suproduct.	
		STABILI	TY ST	UDY DATA	
Man	ufacturer of API	CTX Lifescienc G.I.D.C, Sachin		Ltd. Block No. 251-252, aujrat India	Sachin Magdalla Road
API	Lot No.	21AK000004			
	ription of Pack tainer closure system)	Alu-alu Blister			
Stabi	lity Storage Condition	Real time : 30°C Accelerated: 40°			
Time	Period	Real time: 6 mor			
Freq	uency	Accelerated: 0, 3 Real Time: 0, 3,			
Batc	h No.	RD/PR21-084/	T1/S1	RD/PR21-084/T1/S2	RD/PR21-084/T1/S2
Batc	h Size	2000 Table	et	2000 Tablet	2000 Tablet
Man	ufacturing Date	09-2021		09-2021	09-2021
Date	of Initiation	08-09-202	1	08-09-2021	08-09-2021
No.	of Batches			03	
	DOCUMENTS / DATA TO BE PROVIDED A		1		Y STUDY DATA
1.	Reference of previous appressibility study data of the		ns with	Not submitted	
2.	Approval of API/ DML/GMP certificate of manufacturer issued by concerned regulauthority of country of origin.				021 issued by Food and on Gujrat State India. The e license to manufacture
3.	Documents for the procurement of API approval from DRAP (in case of import).		I with		
4.	Data of stability batches will be supported attested respective documents like chromatog Raw data sheets, COA, summary data sheets of the stability batches will be supported attested respective documents like chromatog		grams,		cal record for product
5.			CFR &	& Firm has submitted certificate of 21 CFR compliance for the HPLC system	
6. Record of Digital data logger for temperature humidity monitoring of stability chambers time and accelerated)				nonitoring of real time and	
Eval	Evaluation by PEC:				
C	Cu No Choutannings communicated Degree area by the films				
1.	1. Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance			onse by the firm	
3.2.3.4.2 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	
	•	
2	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	
1	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.	
	or the drug substance manufacturer.	

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 4004mg Propylene glycol3mg
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

	S		substance.	substance.	
	(Conditions & duration of Stability studies)		study data of 3 batches IV-A conditions Polyethylene Glycols	Polyethylene Glycol: Firm has submitted stability study data of 3 batches of drug substance as per zone	
			its description, c development, manufa and process control, control of excipient specifications, analyti analytical procedures, specifications, refere	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
	Dissolution Profile	alence and Comparativ	equivalence for their p	results of pharmaceutical product against systane drops	
	Analytical method v	validation/verification o	of Firm has submitted v substance and the drug	erification studies of the drug g product.	
		STABILITY S	TUDY DATA		
	Manufacturer of API Propylene glycol Germany. Polyethylene Gly Germany. API Lot No. Propylene glycol: Polyethylene Glycol: Polyethylene Glycol		Merck KGaA Frankfur	ter Str 250 64271 Darmstadt	
	Description of Pack (Container closure system) LDPE plastic bottle				
Stabili	ity Storage Condition	Real time : 30°C ± 2°C Accelerated: 40°C ± 2°			
Time	Period	Real time: 6 months Accelerated: 6 months			
Freque	ency	Accelerated: 0, 3, 6 (Macelerated: 0, 3, 6 (The state of the s		
Batch	No.	SB-01	SB-02	SB-03	
Batch	Size	4.5 L	4.5 L	4.5 L	
Manu	facturing Date	01-2022	01-2022	01-2022	
Date of	of Initiation	18-01-2022	18-01-2022	18-01-2022	
No. of	No. of Batches		03	03	
	DOCUMENTS / DAT	A TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA	
1	Reference of previous approval of applications with stability study data of the firm (if any)		for Bufen Injection	100mg. The inspection was 018 and was considered by the	
1	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).	Locally purchased
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	Firm has submitted audit trail report of stability testing
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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 275 th 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.	Justify 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	
0.	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	
<i>,</i> .	detailed mehod of manufacturing is not submitted in	
	section 3.2.P.3.3.	
8.	Justify why assay test is not included in the	
0.	specifications of drug product.	
9.		
7.	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.	

	API from Martin Dow.			
Decision: Registration Board deferred the case for submission of reply to the above cited sh				
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 4004mg Propylene glycol3mg		
	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.
		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 Substar	nce:	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 Produc	t:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equival Dissolution Profile	lence and Comparative	· · · · · · · · · · · · · · · · · · ·
Analytical method va	alidation/verification of	Firm has submitted verification studies of the drug substance and the drug product.
	STABILITY ST	UDY DATA
Germany.		rck KGaA Frankfurter Str 250 64271 Darmstadt Merck KGaA Frankfurter Str 250 64271 Darmstadt
API Lot No. Propylene glycol: K505 Polyethylene Glycol: K		
Description of Pack (Container closure system)	LDPE plastic bottle	
Stability Storage Condition Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		

Time Period	Real time: 6 months Accelerated: 6 month	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 Pafaranca of prayious	Reference of previous approval of applications with Firm has referred to its previous inspection conducted				

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 282 nd meeting of RB.
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).	Locally purchased
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	Firm has submitted audit trail report of stability testing
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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 275 th 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.	Justify 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	
7	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	
0.	specifications of drug product.	
9.	Justify how validation studies of the drug product	
<i>)</i> .	has been performed since no assay method has been	
	provided.	
10.	Submit GMP ccertificate of the drug substance	
10.	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.	

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 HCl75mg
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) P No. 48, 49 & 50, 209, 210 & 211 Phase-II, ID Pashamylaram Sangareddy Dist, Telangana, India
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-I template. Firm has summarized information relat to nomenclature, structure, general propertic solubilities, physical form, manufacture description of manufacturing process and control impurities, specifications, analytical procedures a its validation, batch analysis and justification specification, reference standard, container closu system and stability studies of drug substance a drug product.
Module-III Drug Substance:	Firm has submitted detailed data for drug substant data related to nomenclature, structure, gene properties, solubilities, physical for manufacturers, description of manufacturing proceand controls, impurities, specifications, analytic procedures and its validation, batch analysis a justification of specification, reference standar container closure system and stability studies of dr substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
Module-III Drug Product:	Firm has submitted data of drug product including description, composition, pharmaceutic development, manufacture, manufacturing process and process control, process validation protococontrol of excipients, control of drug produspecifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or material container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutic equivalence for their product against Tapento Tablet of Sami Firm has submitted results of CDP studies for the

			product a	against Ta	pento IR Tablet of Sami
	product			Firm has submitted report of verification studies of analytical method for the drug substance and product.	
		STABILIT	Y STUDY DA	TA	
Manu	facturer 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 L	ot No.	TPD01190001/U-1			
	iption of Pack ainer closure system)	Alu-Alu Blister			
Stabil	ity Storage Condition	Real time : 30°C ± 2 Accelerated: 40°C ±			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	ency		Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch	No.	T-001	T-002	2	T-003
Batch	Size	5000 Tablet	5000 Ta	blet	5000 Tablet
Manu	facturing Date	11-2021	11-202	21	11-2021
Date of	of Initiation	29-11-2021	29-11-20	021	29-11-2021
No. o	f Batches			03	
	DOCUMENTS / DAT	A TO BE PROVIDE	ED ALONG W	TTH STA	ABILITY STUDY DATA
1.	Reference of previous with stability study data		tions NA		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		copy of C		ificate issued by DCA Government a issued on 09-10-2020.
3.	Documents for the prapproval from DRAP (in		with		
4.	7 11 7		ams, batches a		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		R & Submitte	Submitted	
6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)				d	
Evalu	ation by PEC:		<u> </u>		
Sr. N		municated		Respon	se by the firm

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	Submitted
	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	Not submitted
	substance performed by drug product manufacturer.	

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.

	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: Cabergoline0.5mg		
	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 A	PI manufacturer.	Teva Pharmaceutical Industries Ltd. 5 Basel Street, P.O. Box 3190 Petach Tikva 4951033, Israel
	Module-II (Quality Ove	erall 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 Subst	ance:	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 Dru (Conditions & duration	-	
	Module-III Drug Product:		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equiva Dissolution Profile	alence and Comparative	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 v product	alidation/verification of	Firm has submitted report of verification studies of analytical method for the drug substance and product.
		STABILITY ST	UDY DATA
		Teva Pharmaceutical Inc Tikva 4951033, Israel	dustries Ltd. 5 Basel Street, P.O. Box 3190 Petach
API Lo	API Lot No. 70235000421		
Description of Pack (Container closure system) Alu-Alu Blister		Alu-Alu Blister	
Stability	Stability Storage Condition Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time Po	eriod	Real time: 6 months Accelerated: 6 months	
Frequer	Frequency Accelerated: 0, 1, 2, 3, 6		(Months)

		Real Time: 0, 3, 6 (Months)	
Batch	ı No.	T-001	T-002	T-003
Batch	n Size	5000 Tablet	5000 Tablet	5000 Tablet
Manu	ufacturing Date	11-2021	11-2021	11-2021
Date	of Initiation	30-11-2021	30-11-2021	30-11-2021
No. o	of Batches		03	
	DOCUMENTS / DATA	A TO BE PROVIDE	ED ALONG WITH STA	ABILITY STUDY DATA
1. Reference of previous approval of applications with stability study data of the firm (if any)		tions 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).		with		
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		ams, batches along with	d complete record of testing of all chromatograms, raw data sheets, data sheets.	
5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing		R & Submitted		

time and accelerated)

6.

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.	

Record of Digital data logger for temperature and Submitted

humidity monitoring of stability chambers (real

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: Levetiracetam750mg
	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,

			and controls, impurit procedures and its v justification of speci	ption of manufacturing process cies, specifications, analytical alidation, batch analysis and ification, reference standard, em and stability studies of drug	
	Stability Studies of Dru (Conditions & duration			Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-B conditions	
	Module-III Drug Product:		its description, c development, manufa and process control, control of excipient specifications, analyti analytical procedures, specifications, refere	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
	Pharmaceutical Equiva Dissolution Profile	alence and Comparati	their product against I Firm has submitted	, , ,	
	Analytical method v product	ralidation/verification		study reports for drug substance as well as drug	
	,	STABILITY S	STUDY DATA		
Manı	nfacturer of API			vate Limited Sy. No. 69, ellore District-524228 Andhra	
API l	Lot No.	LT0280420			
	ription of Pack tainer closure system)	Alu-alu Blister			
Stabi	lity Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time	Period	Real time: 6 months Accelerated: 6 month	s		
Frequ	uency	Accelerated: 0, 3, 6 (I Real Time: 0, 3, 6 (M	•		
Batcl	ı No.	21PD-3584-13-T	21PD-3595-14-T	21PD-3596-15-T	
Batcl	n Size	2500 Tablet	2500 Tablet	2500 Tablet	
Manu	ıfacturing Date	03-2021	03-2021	03-2021	
Date	of Initiation	01-04-2021	01-04-2021	01-04-2021	
No. o	of Batches		03		
	DOCUMENTS / DATA	A TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA	
1.	stability study data of the firm (if any)			05-12-2019 and the case was	
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		PI Firm has submitted cory by Drug Control Ac	Firm has submitted copy of GMP certificate issued	

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.	•
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.		Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evalu	uation by PEC:	
Decis	sion: 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: Rebamipide100mg	
	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 A	PI manufacturer.	Jiangxi Synergy Pharmaceutical Co., Ltd Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, P.R.China
Module-II (Quality Ove	erall 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 Subst	ance:	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 Dru (Conditions & duration		Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-B conditions.
Module-III Drug Produ	ct:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equiva Dissolution Profile	alence and Comparative	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 v product	alidation/verification of	Firm has submitted report of verification studies of analytical method for the drug substance and product.
	STABILITY ST	UDY DATA
Manufacturer of API	Jiangxi Synergy Pharma Fengxin, Jiangxi Provinc	aceutical Co., Ltd Jiangxi Fengxin Industrial Park, e, P.R.China
API Lot No.	05-20210624C	
Description of Pack (Container closure system)	Alu-Alu Blister	
Stability Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$	65% ± 5%RH

		1			
		Accelerated: 40°C ±	Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Period			Real time: 6 months Accelerated: 6 months		
Frequency			Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batc	h No.	T-001	T-002	T-003	
Batc	h Size	5000 Tablet	5000 Tablet	5000 Tablet	
Man	ufacturing Date	03-2022	03-2022	03-2022	
Date	of Initiation	01-04-2022	01-04-2022	01-04-2022	
No.	of Batches		03		
	DOCUMENTS / DAT	TA TO BE PROVIDE	ED ALONG WITH STA	LONG WITH STABILITY STUDY DATA	
1.	Reference of previous with stability study data	**	tions NA		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		tory Translated Copy of	f DML certificate issued by CFDA 5-11-2025 is submitted.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		with		
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		ams, batches along with	d complete record of testing of all a chromatograms, raw data sheets, y data sheets.		
5.	5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing		R & Submitted		
6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)					

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of me-too status since fee of	Mucosta Tablet by Otsuka
2.	generic application is submitted. 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 Medoxomil40mg
	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

			studies of drug substance and	
Module-III Drug Substa	nce:	related to nomen properties, solubi manufacturers, descrip and controls, impuring procedures and its valuatification of spec	detailed drug substance data clature, structure, general ilities, physical form, ption of manufacturing process ties, specifications, analytical ralidation, batch analysis and iffication, reference standard, em and stability studies of drug	
	(Conditions & duration of Stability studies)		ability study data of 3 batches ooth accelerated as well as real accelerated stability data is 2° C / $60\% \pm 5\%$ RH for 6 e stability data is conducted at oths.	
Module-III Drug Produc	Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
			charmaceutical equivalence of the innovator's product Edarbi CDP results of their product 's product Edarbi Tablet in 3	
Analytical method va product	alidation/verification o		analytical method validation ag substance as well as drug	
·	STABILITY S'	TUDY DATA		
Manufacturer of API	CTX Lifesciences Pv G.I.D.C, Sachin Surat		252, Sachin Magdalla Road	
API Lot No.	19AK00006			
Description of Pack (Container closure system)	Alu-alu Blister			
Stability Storage Condition Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$				
Time Period Real time: 6 months Accelerated: 6 months				
Frequency	requency Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mon			
Batch No.	T013	T014	T015	
Batch Size	1200 Tablet	1200 Tablet	1200 Tablet	
Manufacturing Date	04-2021	04-2021	04-2021	

Date	Date of Initiation 04-2		04-2021	04-2021
No. of Batches		03	03	
	DOCUMENTS / DATA	ALONG WITH STABI	LITY STUDY DATA	
1.	stability study data of the firm (if any)			th February 2019 and the case
2.	authority of country of origin.		ry G/25/1723) dated 29- Drugs Control Admini certificate specifies th	by of Retention of License (No. 01-2021 issued by Food and stration Gujrat State India. The lat the license to manufacture a 24/01/2021 to 23/01/2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).		cleared dated 03-07	7-2019 specifying 0.540Kg l potassium. The invoice is
4.	Data of stability batches attested respective docume Raw data sheets, COA, sur	nts like chromatogram		alytical record for product
5.	Compliance Record of HI audit trail reports on produ		& Firm has submitted cer for the HPLC system	rtificate of 21 CFR compliance
6.				record of data logger for lity monitoring of real time and nambers.
	proposed shelf life and the registration applica	on accelerated studie tion. form process valida	s for six months as per t	stability studies throughout he commitment submitted in hes as per the commitment
156.	1			ceuticals Plot # 84/1, Block A, Estate, Hattar, Pakistan
	Name, address of Manuf	acturing site.	M/s Aulton Pharmace Phase 5, Industrial Es	euticals Plot # 84/1, Block A, tate, Hattar, Pakistan
	Status of the applicant		☑ Manufacturer☐ Importer	
			\square Is involved in none	of the above (contract giver)
	GMP status of the firm			opy of GMP certificate of the
	GMP status of the firm Evidence of approval of	manufacturing facility	Firm has submitted of firm based on inspection Firm has submitted conformal Manufacturing Licen	opy of GMP certificate of the
		manufacturing facility	Firm has submitted confirm based on inspection Firm has submitted confirm has submitted confirm Licenter 25-11-2021. The letter	opy of GMP certificate of the ion dated 11-12-2020. opy of letter of renewal of Drug se (DML No. 000828) dated er specifies Tablet (General) (NDP)

	□ 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 Medoxomil80mg
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 $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$ 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 Equival Dissolution Profile	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 va	alidation/verification	of Firm has submitted	analytical method validation ig substance as well as drug	
	STABILITY	STUDY DATA		
Manufacturer of API	CTX Lifesciences F G.I.D.C, Sachin Sura		252, Sachin Magdalla Road	
API Lot No.	19AK00006			
Description of Pack (Container closure system)	Alu-alu Blister			
Stability Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time Period	Real time: 6 months Accelerated: 6 month	s		
Frequency	Accelerated: 0, 3, 6 (Meal Time: 0, 3, 6 (Meal			
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		
1		ALONG WITH STABI		
			ction for aultadex capsule has the February 2019 and the case meeting.	
manufacturer issued by	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		by of Retention of License (No. 01-2021 issued by Food and stration Gujrat State India. The lat the license to manufacture a 24/01/2021 to 23/01/2026.	
	Documents for the procurement of API with approval from DRAP (in case of import).		copy of commercial invoice 7-2019 specifying 0.540Kg l potassium. The invoice is DRAP.	
attested respective docume	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		alytical record for product	
audit trail reports on produ	ct testing	for the HPLC system	rtificate of 21 CFR compliance	
humidity monitoring of stime and accelerated)			record of data logger for lity monitoring of real time and nambers.	
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,

		impurities, specificati its validation, batch specification, reference	acturing process and controls, ons, analytical procedures and analysis and justification of ce standard, container closure studies of drug substance and
Module-III Drug Substan	nce:	related to nomen properties, solubi manufacturers, descripand controls, impuring procedures and its vijustification of spec	detailed drug substance data clature, structure, general ilities, physical form, ption of manufacturing process ties, specifications, analytical ralidation, batch analysis and ification, reference standard, em and stability studies of drug
Stability Studies of Drug (Conditions & duration of		of drug substance at be time conditions. The conducted at 25°C ±	ability study data of 3 batches both accelerated as well as real accelerated stability data is $2 ^{\circ}\text{C} / 60\% \pm 5\%$ RH for 6 e stability data is conducted at onths.
Module-III Drug Produc	Module-III Drug Product:		lata of drug product including omposition, pharmaceutical acture, manufacturing process process validation protocols, s, control of drug product, ical procedures, validation of batch analysis, justification of ence standard or materials, em and stability.
Pharmaceutical Equival Dissolution Profile	Pharmaceutical Equivalence and Comparative Dissolution Profile		charmaceutical equivalence of the innovator's product Edarbi CDP results of their product 's product Edarbi Tablet in 3
Analytical method va	alidation/verification o		analytical method validation ig substance as well as drug
	STABILITY S	TUDY DATA	
Manufacturer of API		Ltd. Block No.82/B, ECF , District-Vadodara Guja	P Road, AT & Post. Karakhadirat, INDIA
API Lot No.	AZP/50150820		
Description of Pack (Container closure system) Alu-alu Blister			
Stability Storage Condition Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Time Period Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0, 3, 6 (Mo	•	
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 STABI	LITY STUDY DATA	
1.	Reference of previous appr stability study data of the f		has been conducted or	Product specific inspection for Empagin XR Tablet has been conducted on 05-12-2019 and the case was approved in 293 rd meeting.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			Control Administration Gujrat	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		cleared dated 01-	12-2020 specifying 1.6Kg l potassium. The invoice is	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			alytical record for product	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		& Firm has submitted cer for the HPLC system	rtificate of 21 CFR compliance	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			record of data logger for lity monitoring of real time and nambers.	
Eval	Evaluation by PEC:				
Deci	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. L E-Zhou City, Hubei Province China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-I template. Firm has summarized information relat to nomenclature, structure, general propertisolubilities, physical form, manufacture description of manufacturing process and control impurities, specifications, analytical procedures a its validation, batch analysis and justification specification, reference standard, container closusystem and stability studies of drug substance a drug product.
Module-III Drug Substance:	Firm has submitted detailed data for both dr substance data related to nomenclature, structure general properties, solubilities, physical for manufacturers, description of manufacturing process and controls, impurities, specifications, analytic procedures and its validation, batch analysis a justification of specification, reference standard container closure system and stability studies of dr substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batch of drug substance at both accelerated as well as retime conditions. The accelerated stability data conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for months. The real time stability data is conducted $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 48 months.
Module-III Drug Product:	Firm has submitted data of drug product includi its description, composition, pharmaceutic development, manufacture, manufacturing process and process control, process validation protoco control of excipients, control of drug produspecifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or material container closure system and stability.

	Dissolution Profile		against U-Progest 100 Firm has not submitte Profile studies and sub	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 valid product	ation/verification of	Firm has submitted re analytical method for		
STA	BILITY STUDY DATA				
Manı	ufacturer of API	Hubei Gedian Humanwell Pharmaceutical co. Ltd. E-Zhou City, Hubei Province China.			
API I	Lot No.	HTT190904			
	ription of Pack tainer closure system)	Alu-PVC PVDC Blis	ter		
Stabi	lity Storage Condition	Real time: 30°C ± 2°C Accelerated: 40°C ± 2			
Time	Period	Real time: 6 Months Accelerated: 6 Month	.s		
Frequ	uency	Real Time: 0, 3, 6 (M Accelerated: 0, 3, 6 (I			
Batch	n No.	039S02	040S02	041S02	
Batch	n Size	75000 Capsule	75000 Capsule	75000 Capsule	
Manu	ufacturing Date	02-2020	02-2020	02-2020	
Date	of Initiation	03-2020	03-2020	03-2020	
No. o	of Batches	03			
DOC	UMENTS / DATA TO BE	PROVIDED ALONG	WITH STABILITY STU	DY DATA	
1.	Reference of previous app with stability study data of		NA		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Written confirmation f to EU valid till 26-10-2	or active substances exported 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.			alytical record of stability	
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			
Evalu	uation by PEC:				

- 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.

59.	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	
	GMP status of the firm	☐ Is involved in none of the above (contract giver) 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

				fication, reference standard, m and stability studies of drug	
			substance.		
	(Conditions & duration of Stability studies) Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile		of drug substance at bottime conditions. The conducted at 40° C \pm months. The real time	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. Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. 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	
			its description, co development, manufact and process control, p control of excipients specifications, analytical analytical procedures, b specifications, referen		
			against U-Progest 200r Firm has not submitted Profile studies and sub		
	Analytical method vali	dation/verification of		Firm has submitted report of verification of analytical method for the drug product.	
STA	BILITY STUDY DATA				
Man	ufacturer of API	Hubei Gedian Humar Province China.	nwell Pharmaceutical co. Lt	td. E-Zhou City, Hubei	
API	Lot No.	HTT171101			
	cription of Pack stainer closure system)	Alu-PVC PVDC Blis	ter		
Stab	ility Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time	e Period	Real time: 6 Months Accelerated: 6 Month	ns		
Freq	uency	Real Time: 0, 3, 6 (M Accelerated: 0, 3, 6 (M			
Batc	h No.	B1194	B1195	B1196	
Batc	h Size	50000 Capsule	50000 Capsule	50000 Capsule	
Man	ufacturing Date	04-2018	04-2018	04-2018	
Date	Date of Initiation 05-2018		05-2018	05-2018	
No.	No. of Batches 03				
DOC	CUMENTS / DATA TO B	E PROVIDED ALONG	WITH STABILITY STUD	DY DATA	
1.	Reference of previous approval of applications with stability study data of the firm (if any)		NA		
2.			Written confirmation for to EU valid till 26-10-2	or active substances exported 023	

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		
Eval	Evaluation by PEC:			

- 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		
	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 Elagolix150mg	
	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-PE 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 batche of drug substance at both accelerated as well as reatime conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65 \pm 5\%$ 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 dru substance and the drug product.

	STABILITY STUDY DATA			
Man			aceuticals Pvt Ltd Plot no a, E Bonangi Visakhapat	
API	Lot No.	6024/3/001/21		
	ription of Pack tainer closure system)	Alu-Alu blister		
Stabi	lity Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Freq	uency	Accelerated: 0, 3, 6 (Macelerated: 0, 3, 6 (
Batc	h No.	ELXL-001	ELXL-002	ELXL-003
Batc	h Size	1500 Tablet	1500 Tablet	1500 Tablet
Man	ufacturing Date	04-2022	04-2022	04-2022
Date	of Initiation	18-04-2022	18-04-2022	19-04-2022
No. o	of Batches	03		
	DOCUMENTS / DATA	TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA
1.	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.			py of GMP certificate issued ninistration Government of 06-04-2022.
3.	· · · · · · · ·			py of commercial invoice DRAP dated 13-12-2021. The Elagolix.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			cord of testing of all batches neets, COA and summary data
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Firm has submitted au	dit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			cord of digital data logger for dity monitoring of real time ty chambers.
Eval	Evaluation by PEC ³ :			

- 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	
	GMP status of the firm	☐ Is involved in none of the above (contract giver) 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 Elagolix200mg
	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 Subst	ance:	data related to nom properties, solubi manufacturers, descrip and controls, impurit procedures and its v justification of speci	etailed data for drug substance nenclature, structure, general dities, physical form, ption of manufacturing process ties, specifications, analytical alidation, batch analysis and diffication, reference standard, em and stability studies of drug	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)		ability study data of 3 batches both accelerated as well as real accelerated stability data is 2° C / $75\% \pm 5\%$ RH for 6 e stability data is conducted at RH for 24 months.	
Module-III Drug Produ	ict:	its description, c development, manufa and process control, control of excipient specifications, analyti analytical procedures,	ata of drug product including omposition, pharmaceutical acture, manufacturing process process validation protocols, s, control of drug product, ical procedures, validation of batch analysis, justification of ence standard or materials, em and stability.	
Pharmaceutical Equiva Dissolution Profile	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 vali	Analytical method validation/verification of product		Firm has submitted verification studies of the drug substance and the drug product.	
	STABILITY ST			
		naceuticals Pvt Ltd Plot no da, E Bonangi Visakhapat		
API Lot No.	6024/3/001/21			
Description of Pack (Container closure system)	Alu-Alu blister			
Stability Storage Condition Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$				
Time Period Real time: 6 months Accelerated: 6 months		as		
Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Monte				
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 / DAT	A TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA	

1.	Reference of previous approval of applications	Firm has referred to their last product specific
	with stability study data of the firm (if any)	inspection conducted for "Empazon 10mg & 25mg
		Tablet", which was conducted on 1st June, 2021, and
		was presented in 307th meeting of Registration
		Board. The general confirms following points:
		The report confirms following points: The HPLC software is 21CFR Compliant.
		Firm has demonstrated Audit trail reports of testing.
2	A 1 CADI/DIMI/CIMB ('C' / CADI	1
2.	Approval of API/ DML/GMP certificate of API	Firm has submitted copy of GMP certificate issued
	manufacturer issued by concerned regulatory	by Drugs Control Administration Government of Andhra Pradesh dated 06-04-2022.
	authority of country of origin.	
3.	Documents for the procurement of API with	Firm has submitted copy of commercial invoice
	approval from DRAP (in case of import).	cleared by AD (I&E) DRAP dated 13-12-2021. The
		invoice specifies 2kg Elagolix.
4.	Data of stability batches will be supported by	Firm has submitted record of testing of all batches
	attested respective documents like chromatograms,	along with raw data sheets, COA and summary data
	Raw data sheets, COA, summary data sheets etc.	sheets.
5.	Compliance Record of HPLC software 21CFR &	Firm has submitted audit trail reports
	audit trail reports on product testing	
6.	Record of Digital data logger for temperature and	Firm has submitted record of digital data logger for
	humidity monitoring of stability chambers (real	temperature and humidity monitoring of real time
	time and accelerated)	and accelerated stability chambers.
Eval	uation by PEC ³ :	

- 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: Aspirin81mg
	Omeprazole40mg
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 ar omeprazole, is indicated for patients who require aspirin for secondary prevention of cardiovascul and cerebrovascular events and who are at risk 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 by 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, Limite Yuquan Road, Huayin City, Shanxi Province, P.R China. Omeprazole: Metrochem API Private Limited Plot No. 62/C/6, Pipe Line Road Phase I, ID Jeedimetla Hyderabad Telangana State India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-P template. Firm has summarized information related to nomenclature, structure, general properties solubilities, physical form, manufactured description of manufacturing process and control impurities, specifications, analytical procedures at its validation, batch analysis and justification specification, reference standard, container closures system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed data for drug substand data related to nomenclature, structure, gener properties, solubilities, physical formanufacturers, description of manufacturing proce and controls, impurities, specifications, analytic procedures and its validation, batch analysis are justification of specification, reference standar 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 3 batches of drug substance at both accelerated well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH f 6 months. The real time stability data is conducted $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65 \pm 5\%$ RH for 24 months. Omeprazole: Firm has submitted stability stud data of 3 batches of drug substance at bo accelerated as well as real time conditions. The stability students are submitted as the submitted stability students.

			accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65 \pm 5\%$ RH for 60 months.	
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 vali	dation/verification of	Firm has submitted verification studies of the drug substance and the drug product.	
		STABILITY	STUDY DATA	
City, Shanxi Province, Omeprazole: Metroch Plot No. 62/C/6, Pipe I		City, Shanxi Province Omeprazole: Metroc	them API Private Limited Line Road Phase I, IDA Jeedimetla Hyderabad	
API Lot No. Aspirin: A2108011		-		
Description of Pack (Container closure system) Alu-Alu blister		Alu-Alu blister		
Stabi	Stability Storage Condition Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Time	Period	Real time: 6 months Accelerated: 6 month	s	
Frequ	uency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batcl	n No.	AOL-001	AOL-002	
Batcl	n Size	5000 Tablet	5000 Tablet	
Manı	ufacturing Date	12-2021	12-2021	
Date	of Initiation	12-2021	12-2021	
No. of Batches 03		03		
	DOCUMENTS / DAT	A TO BE PROVIDED	ALONG WITH STABILITY STUDY DATA	
1.	Reference of previous ap with stability study data of		Firm has referred to their last product specific inspection conducted for "Empazon 10mg & 25mg Tablet", which was conducted on 1 st 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.	
			1 mm has demonstrated Addit 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 PEC³:

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	Updated analytical method has been submitted.
	which do not contain any time point	
	for dissolution test.	
9.	Submit valid GMP certificate of the	Submitted
	manufacturer of omeprazole, since	
	the submitted GMP is not valid.	
10.	Submit document for import of	Submitted
	omeprazole since the submitted	
	invoice is of Surge Laboratories.	

- 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.

Plot No. 33, t No. 33,	
t No. 33,	
ontract giver)	
certificate 14-10-2021.	
newal of es Tablet	
☑ New Drug Product (NDP)☐ Generic Drug Product (GDP)	
ibitor	
aspirin and tho require cardiovascular are at risk of lcers.	
i -	

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 Equival Dissolution Profile	ence and Comparative	equivalence for the against Yosprala table	esults of CDP for their product	
	Analytical method valid product	ation/verification of	Firm has submitted v substance and the dru	verification studies of the drug g product.	
		STABILITY ST	ΓUDY 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/21	01012		
	ription of Pack tainer closure system)	Alu-Alu blister			
Stab	ility Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Time	e Period	Real time: 6 months Accelerated: 6 months		· · · · · · · · · · · · · · · · · · ·	
Freq	Frequency Accelerated: 0, 3, 6 (Morreal Time:				
Batc	h No.	AOH-001	AOH-002		
Batc	h Size	5000 Tablet	5000 Tablet		
Man	ufacturing Date	12-2021	12-2021		
Date	of Initiation	12-2021	12-2021		
No.	of Batches	03		,	
	DOCUMENTS / DATA	TO BE PROVIDED A	LONG WITH STABI	LITY STUDY DATA	
1.			inspection conducted the Tablet", which was consumed in 307th Board. The report confirms for The HPLC software is		
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).				
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			cord of testing of all batches neets, COA and summary data	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Firm has submitted au	dit trail reports	

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

Evaluation by PEC³:

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	Firm has submitted revised label label as under:
	innovator's product along with	Each Film Coated Tablet Contains:
	submission of full fee.	Aspirin (delayed release)325mg
		Omeprazole (immediate release)40mg
2.	Submit evidence of approval of	Due to commercial reason YOSPRALA has been
	applied formulation in reference	discontinued from the market. Moreover a generic
	regulatory authorities, since the	version of this product has also received tentative
	submitted reference of USFDA have	approval from USFDA as well.
	been discontinued without specifying	
	the reason for discontinuation.	
3.	Submit real time stability study data	Submitted
	of 3 batches of aspirin conducted as	
	per zone IV-A conditions.	
4.	Justify the use of working standard of	Omeprazole API was taken as loan from Surge
	omeprazole from Surge Laboratories,	laboratories therefore the same working standard was
	since the API supplier for omeprazole	also used.
	is Metrochem India.	
5.	Provide complete method of	Detailed method is submitted.
	manufacturing since no step	
	specifying the manufacturing of	
	omeprazole layer is provided.	
6.	Justify the process validation in	Complete process validation is submitted.
	which the step of manufacturing of	
	omeprazole layer is not include	
	although being the most critical step.	
7.	Submit analytical method for testing	Analytical method is submitted.
	of the drug product	
8.	Justify the drug product specification	Updated analytical method has been submitted.
	which do not contain any time point	
	for dissolution test.	
9.	Submit valid GMP certificate of the	Submitted
	manufacturer of omeprazole, since	
	the submitted GMP is not valid.	
10.	Submit document for import of	Submitted
	omeprazole since the submitted	
	invoice is of Surge Laboratories.	

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 Sodium4mg
	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 5 th 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 Su (Conditions & duration of S		Stability study conditions: Long term: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ for 36 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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 Equiv Comparative Dissolution Pr		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 validati product	on/verification of	Firm has submitted analytical method verification study reports for drug product.		
	STABILITY S	STUDY DATA		
Manufacturer of API	Address: No. 1 and medical Ray	ANYU PHARMCEUTICALS CO., LTD. 5, Donghai 5 th Avenue, Zhejiang Provincial chemical w Materials he, Taizhou City, Zhejiang Province, China.		
API Lot No.	11001-210513			
Description of Pack (Container closure system)	Alu Alu foil	Alu Alu foil		
Stability Storage Condition	Real time: 30°C	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$		

			Accelerated:	$40^{\circ}\text{C} \pm 2^{\circ}\text{C}$	/ 75% ± 5%RH	
Time Period			Real time: 6 months Accelerated: 6 months			
Frequency			Accelerated: Real Time: 0,		· · · · · · · · · · · · · · · · · · ·	
Batch No.			ST1A	A126	ST1A127	ST1A128
Batch Size	e		3000 T	ablets	3000 Tablets	3000 Tablets
Manufact	uring Date		02-2	2022	02-2022	02-2022
Date of In	itiation		08-02	-2022	08-02-2022	08-02-2022
No. of Ba	tches				03	
	DOCUMEN	NTS / DATA TO	BE PROVIDI	ED ALONG	WITH STABILITY STUD	Y DATA
1.		with stability stu	approval of dy data of the			
2.	API manuf		by concerned	issued by C	ML No# Zhejiang 20050433 China food and Drug Contro 06-2020 and valid until 16.0	l administration
3.		for the procure val from DRAP		Firm has submitted copy of form 3, form 6, form 7 and		
4.	by attested chromatogra	ility batches will respective doc ams, Raw data s ta sheets etc.	cuments like			or product testing.
5.				Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.		
6.	temperature	and humidity r hambers (real	nonitoring of	temperatur	submitted record of digite and humidity monitoring stability chambers.	
	of Evaluator					
1.	Section 1.6.5	Valid Good I (GMP) certif Substance ma	Manufacturing License of Manufacturing Practice ificate of the Drug nanufacturer issued by atory authority of country		Reply Submitted	
2.	2.3.R.1.1	Provide copy of Record (BMR) drug product for data is provide 3.2.P.8.3) for all the bor which stabiled in Module	patches of ity studies 3 section	Submitted	
3.	3.2.S.4.1	product manuf	e specifications by Drug facturer specified test of specification claimed are		Drug substance specific product manufacturer s sodium is for identification substance manufacturer a specification, identification mentioned in USP mo	pecified test of tion only, Drug lso mentioned in

4. 3.2.P.8	Submit commercial invoice attested by DRAP. Retable No. of drug substance.	product manufacturer drug substance method is completely harmonized with USP method. Method of product manufacturer of dug substance and USP method has been attached • Form 6 issued by DRAP along-with invoice and Airway bill attached.
	 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 	 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.
	monitoring of stability chambers (real time and accelerated)	

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

- 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)		

Intend	ded use of pharmaceutical product	□ Domestic sale
		☐ Export sale☑ Domestic and Export sales
Dy N	Jo. and date of submission	Dy. No. 23140 dated 16-08-2022
	ls of fee submitted	PKR 30,000/- Deposit Slip# 62259464703
	proposed proprietary name / brand name	Lumont 5mg Tablet
	gth / concentration of drug of Active	Each Chewable Tablet Contains:
Pharn	naceutical ingredient (API) per unit	Montelukast as Sodium5mg
Pharn	nacotherapeutic Group of (API)	Light green color, round shaped biconvex chewable tablets.
Pharn	naceutical form of applied drug	Leukotriene receptor antagonist
Refer	ence to Finished product specifications	USP
Propo	osed Pack size	2×7's
Propo	osed unit price	As per SRO
The st	tatus in reference regulatory authorities	SINGULAIR 5mg Chewable tablet, by Organon of USFDA Approved.
For ge	eneric 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 5 th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
Modu	ile-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.
Modu	lle-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.
	lity Studies of Drug Substance ditions & duration of Stability studies)	Stability study conditions: Long term: $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$ for 36 months Accelerated: $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%$ for 6 months
Modu	ile-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch

			•	justification of speci or materials, container		
	Pharmaceutical Equival Comparative Dissolution Profi		against th Pharma (P Physical a Assay). CDP has Chewable media (pF	utical Equivalence have Myteka 5mg Chewab vt) Ltd performing quality ppearance, Uniformity of been performed against Tablet by Hilton Pharma I 1.2), Acetate Buffer (pl 6.8). The f2 values are in	tests (Identification, weight, Dissolution, the 'Myteka 5mg a (Pvt) Ltd in Acidic H 4.5) & Phosphate	
	Analytical method validatio product	n/verification		submitted analytical mether drug product.	nod verification study	
		STABILIT	Y STUDY DA	TA		
Manufact	urer of API	Address: No and medical I	o. 15, Donghai Raw Materials	RMCEUTICALS CO., L 5 th Avenue, Zhejiang Pro City, Zhejiang Province,	ovincial chemical	
API Lot N	No.	11001-21051	3			
	on of Pack or closure system)	Alu Alu foil	Alu Alu foil			
Stability S	Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$				
Time Peri	od	Real time: 6 months Accelerated: 6 months				
Frequency	y		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No.		ST1A	A129	ST1A130	ST1A131	
Batch Siz	e	3000 T	Tablets	3000 Tablets	3000 Tablets	
Manufact	uring Date	02-2	2022	02-2022	02-2022	
Date of In	nitiation	08-02	-2022	08-02-2022	08-02-2022	
No. of Ba	tches		03			
	DOCUMENTS / DATA TO	BE PROVIDE	ED ALONG W	/ITH STABILITY STUD	Y DATA	
1.	Reference of previous applications with stability stufirm (if any)	approval of ady data of the				
2.	· · · · · · · · · · · · · · · · · · ·		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.		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 by attested respective do chromatograms, Raw data summary data sheets etc.	cuments like	Firm has subi	mitted analytical record fo	or product testing.	

5.					mitted certificate of 21 CFR compliance for the n along with audit trail report for product	
		testing		testing.		
6.		_	nd humidity monitoring of	temperature	abmitted record of digital data logger for and humidity monitoring of real time and ability chambers.	
Re	marks c	f Evaluator:				
	S.No	Section	Shortcoming		Reply	
	1.	1.6.5	Valid Drug Manufacturing Valid Good Manufacturi (GMP) certificate of the Drumanufacturer issued b regulatory authority of cour	ing Practice ug Substance y relevant	Submitted	
	2.	2.3.R.1.1	Provide copy of Batch M Record (BMR) for all the ba product for which stability s provided in Module 3 section	fanufacturing atches of drug atudies data is on 3.2.P.8.3	Submitted	
	3.	3.2.\$.4.1	Drug substance specification product manufacturer specification while specification USP. Clarify.	eified test of	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 commerce attested by DRAP. Batch No of drumentioned in stabil different than mentioned on subby drug product ma Clarification is received the eluted main pear the chromatogram sensitivity solution solution was of memontelukast dicycles since the specified repeak is montelukast chromatogram shee Submit 6th month st studies data of drug since you have subin data of only 3 mont Record of Digital defor temperature and monitoring of stabilichambers (real time and accelerated) 	ig substance ity studies is Batch No mitted COA mufacturer. quired either k depicted in a sheets of and standard ontelukast or ohexylamine, name of main st in all the ets. Tability g product mitted the hs. ata logger I humidity lity	 Form 6 issued by DRAP alongwith 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

- 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.

	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. 23141 dated 16-08-2022			
-	Dy. No. and date of submission				
Details of fee submitted		PKR 30,000/- Deposit Slip# 22797145			
	The proposed proprietary name / brand name Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Lumont 10mg Tablet Each film coated tablet contains: Montelukast as sodium10mg Green color, round shaped biconvex film coated tablets. Leukotriene receptor antagonist USP 2×7's As per SRO SINGULAIR 10mg tablet, by Organon of USFDA Approved. Myteka 10mg Chewable Tablet by Hilton Pharma (Pvt) Ltd		
	Pharmaceutical form of applied drug				
	Reference to Finished product specifications				
	Proposed Pack size				
	Proposed unit price				
	The status in reference regulatory authorities				
	For generic drugs (me-too status)				
	Name and address of API manufacturer.	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. Address: No. 15, Donghai 5 th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province China.			
F	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template			

		physical manufactu analytical and justif container	fure, structure, general pro- form, manufacturers, aring process and cont procedures and its validation of specification, closure system and stabil and drug product.	description of rols, specifications, ation, batch analysis reference standard,	
Module-III Drug Substance:		to nome solubility' manufactu analytical and justif	submitted detailed drug submitted detailed drug submitted; structure, so so, physical form, manufacturing process and conting procedures and its validation of specification, closure system and stability.	general properties, turers, description of rols, specifications, ation, batch analysis reference standard,	
Stability Studies of Drug Sub (Conditions & duration of St		Long term	tudy conditions: a: 30°C ± 2°C / 65% ± 5% ed: 40°C ± 2°C / 75% ± 5%		
Module-III Drug Product:	Module-III Drug Product:		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
Pharmaceutical Equiva Comparative Dissolution Pro		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 validatio product	n/verification of	Firm has submitted analytical method verification study reports for drug product.			
	STABILITY S	STUDY DA	ATA		
Manufacturer of API	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. Address: No. 15, Donghai 5 th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.			ovincial chemical	
API Lot No.	11001-210513				
Description of Pack (Container closure system)	Alu Alu foil				
Stability Storage Condition	Real time: 30°C Accelerated: 40°				
Time Period	Real time: 6 months Accelerated: 6 months				
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No.	ST1A13	35	ST1A136	ST1A137	

Batch S	Size		3000 T	Γablets	3000 Tablets	3000 Tablets	
Manufacturing Date		02-2022		02-2022	02-2022		
Date of	Date of Initiation 08-02		2-2022	08-02-2022	08-02-2022		
No. of I	Batches				03	1	
	DOCUME	NTS / DATA TO	BE PROVIDI	ED ALONG W	/ITH STABILITY STUD	Y DATA	
1.		s with stability stu	approval of dy data of the				
2.	API manu		by concerned	issued by Chi	No# Zhejiang 20050431 na food and Drug Contro 2020 and valid until 16.0	l administration	
3.		for the procure eval from DRAP		Commercial	omitted copy of form 3, Invoice # TY121675 Kg of Montelukast Sod	dated: 29-07-2021	
4.	by attested chromatogr	bility batches will d respective doc rams, Raw data s ata sheets etc.	cuments like		mitted analytical record fo	or product testing.	
5.					Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.		
6.		e and humidity r chambers (real	nonitoring of	temperature	abmitted record of diginal and humidity monitorinability chambers.		
Remar	ks of Evaluato	r:		•			
S.No	Section	Shortcoming			Reply		
1.	1.6.5	Valid Drug Mar Good Manufa certificate of manufacturer is authority of cou	cturing Practing the Drug sued by releva	etice (GMP) g Substance	Submitted		
2.	2.3.R.1.1	Provide copy Record (BMR) product for white provided in Moo	of Batch N for all the ba ich stability s	tches of drug tudies data is	Submitted		
3.	3.2.S.4.1	Drug substance specification product manufacturer specification clands. Clarify.		ified test of	Drug substance speci- product manufacturer sodium is for identification, identification, identification, identification also mentioned in USP product manufacturer method is completely has method. Method of product substance and US attached	specified test of ication only, Drug r also mentioned in ation of sodium is monograph. Hence drug substance armonized with USP duct manufacturer of	
4.	3.2.P.8	by DRABatch mention	AP. No of dru ned in stabili	ryoice attested g substance ty studies is No mentioned	invoice and AirBatch number	by DRAP along-with way bill attached. of drug substance tability studies is a error, however	

on submitted COA by drug product submitted COA by firm Batch no. is manufacturer. correct. Clarification is required either the The eluted main peak depicted in eluted main peak depicted in the chromatogram sheets chromatogram sheets of sensitivity sensitivity and standard solutions is solution and standard solution was of Montelukast dicylohexylamine. of montelukast or montelukast The relevant chromatogram of dicyclohexylamine, Primary USP reference standard of since specified name of main peak is Montelukast dicyclohexylamine montelukast in with identified peak is attached along-with COA chromatogram sheets. 6th month stability data has been Submit 6th month stability studies data of drug product since you submitted on 4-10-2022. However have submitted the data of only 3 duplicate stability data. months. Submitted. 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)

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

- 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		

Ltd, Reg. No. 086609 Name and address of API manufacturer. Qilu Antibiotics Pharmaceutical Co., Ltd. No. 84 Dongjia Town, Licheng District, Jinan, Shandor Province, China Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-PD templat Firm has summarized information related nomenclature, structure, general properties, solubilities physical form, manufacturers, description of manufacturing process and controls, specification analytical procedures and its validation, batch analys and justification of specification, reference standar container closure system and stability studies of dr. substance and drug product.	Details of fee submitted	PKR 30,000/- Deposit Slip# 4570831647		
Pharmaceutical ingredient (API) per unit Pharmaceutical form of applied drug Pharmaceutical form of applied drug Proposed Pack size Proposed Pack size Proposed Pack size Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Oxidil IV Injection 2gm by Sami Pharmaceutical (Pvt. Ltd., Reg. No. 086609 Name and address of API manufacturer. Oilu Antibiotics Pharmaceutical Co., Ltd. No. 84 Dongjia Town, Licheng District, Jinan, Shandor Province, China Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-PD templat Firm has submitted QOS as per with optication analytical procedures and its validation, batch analyse and justification of specification, reference standar container closure system and stability studies of dr. substance. Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Firm has submitted detailed drug substance data relate to nomenclature, structure, general properties solubility's, physical form, manufacturers, description manufacturing process and controls, specification analytical procedures and its validation, batch analys and justification of specification, reference standar container closure system and stability studies of dr. substance. Stability Studies of Drug Substance (Conditions & duration of Stability studies) Firm has submitted data of drug product including i description, composition, pharmaceutical development manufacture, manufacturing process and process control or excipient control of drug product, specifications, analytic procedures, validation of analytical procedures, validation of analytical procedures standard or materials, container closure system as stability. Pharmaceutical Equivalence and C	The proposed proprietary name / brand name	Maxef 2gm Injection		
Pharmaceutical form of applied drug Reference to Finished product specifications Reference to Finished product specifications Proposed Pack size Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Oxidil IV Injection 2gm by Sami Pharmaceutical (Pvt Ltd, Reg. No. 086609 Name and address of API manufacturer. Oliu Antibiotics Pharmaceutical Co., Ltd. No. 84 Dongjia Town, Licheng District, Jinan, Shandor Province, China Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-PD templat Firm has summarized information related in momenclature, structure, general properties, solubilitie physical form, manufacturers, description of manufacturing process and controls, specification analytical procedures and its validation, batch analys and justification of specification, reference standar container closure system and stability studies of drug substance and drug product. Module-III Drug Substance: Firm has submitted detailed drug substance data relate to nomenclature, structure, general propertie solubility's, physical form, manufacturers, description of manufacturing process and controls, specification analytical procedures system and stability studies of drug substance data relate to nomenclature, structure, general propertie solubility's, physical form, manufacturers, description of substance and drug product. Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Firm has submitted data of drug product including it description, composition, pharmaceutical development manufacture, manufacturing process and process one manufacture, manufacturing process and process control of drug product, specifications, analytic procedures, validation of analytical procedures, bat analysis, justification of analytical procedures, bat analysis, justification of specifications, reference standard or materials, container closure system at stability. Pharmaceutical Equivalence and Comparative	· ·			
Reference to Finished product specifications Proposed Pack size Proposed unit price As per SRO CEFTRIAXONE by SANDOZ INC of USFDA Oxidil IV Injection 2gm by Sami Pharmaceutical (Pvt Ltd, Reg. No. 086609) Name and address of API manufacturer. Qilu Antibiotics Pharmaceutical Co., Ltd. No. 84 Dongjia Town, Licheng District, Jinan, Shandor Province, China Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QOS-PD templat Firm has summarized information related in omenclature, structure, general properties, solubilitie physical form, manufacturers, description of manufacturing process and controls, specification analytical procedures and its validation, batch analys and justification of specification, reference standar container closure system and stability studies of dresubtance and drug product. Module-III Drug Substance: Firm has submitted detailed drug substance data relate to nomenclature, structure, general properties solubility's, physical form, manufacturers, description of manufacturing process and controls, specification analytical procedures and its validation, batch analys and justification of specification, reference standar container closure system and stability studies of dresubtance. Stability Studies of Drug Substance (Conditions & duration of Stability studies) Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Firm has submitted data of drug product including i description, composition, pharmaceutical developmen manufacture, manufacturing process and process controprocess validation of analytical procedures, batc analysis, justification of specifications, reference standard or materials, container closure system at stability. Pharmaceutical Equivalence And Comparative Dissolution Profile Pharmaceutical Equivalence Tirm has submitted pharmaceutical equivalence of the product against the innovator's product Oxidil I Injection 2gm by Sami Pharmaceutical (Pvt.) Ltd, Re No. 086609 by performing quality tests (description,	Pharmacotherapeutic Group of (API)	Third-Generation Cephalosporin antibiotics.		
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		STABILIT	Y STUDY DA	ΛTA	
		ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. Address: No. 15, Donghai 5 th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.			
API Lot N	No.	1066DJ81HC		<u> </u>	
	on of Pack er closure system)	Packed in 20 WFI	ml clear glass	sealed vial containing d	ry powder with 10ml
Stability S	Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time Per	iod	Real time: 6 i Accelerated:			
Frequenc	у		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No		TR-1/MX	KF 2g Inj	TR-2/MXF 2g Inj	TR-3/MXF 2g Inj
Batch Siz	e	2000	vials	2000 vials	2000 vials
Manufact	turing Date	10-2	2021	10-2021	10-2021
Date of Ir	nitiation	24-10	-2021	24-10-2021	24-10-2021
No. of Ba	atches			03	
	DOCUMENTS / DATA TO	BE PROVIDI	ED ALONG W	VITH STABILITY STUI	DY DATA
1.	Reference of previous approval of applications with stability study data of the firm (if any)		 the 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.	API manufacturer issued by concerned		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		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.			mitted analytical record f	or product testing.
5.			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		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		

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: Silodosin4mg		
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 5 th 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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ for 24 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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 an 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 product		reports for	drug product.	od verification study	
		STABILIT	Y STUDY DA	ATA		
Manufactu	arer of API	Address: No and medical I	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. Address: No. 15, Donghai 5 th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.			
API Lot N	lo.	13001-20060	3-2			
Description (Contained	on of Pack r closure system)	Alu Alu foil				
Stability S	Storage Condition		0°C ± 2°C / 65% ± 5%RH 40°C ± 2°C / 75% ± 5%RH			
Time Period Real time: 6 r Accelerated: 0						
Frequency	/		0, 3, 6 (Months) , 3, 6 (Months)			
Batch No.		TR-00	08-21	TR-009-21	TR-012-21	
Batch Size	2	1500 C	apsule	1500 Capsule	1500 Capsule	
Manufactu	uring Date	04-2	.021	04-2021	04-2021	
Date of In	itiation	26-04-2021		26-04-2021	26-04-2021	
No. of Ba	tches		03			
	DOCUMENTS / DATA TO	BE PROVIDE	ED ALONG W	VITH STABILITY STUD	Y DATA	
		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.	* *		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		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			

Remarks	accelerated) of Evaluator:					
6.	temperature and stability cham	l humidity m	onitoring of	temperature a	bmitted record of digital data logger and humidity monitoring of real time ability chambers.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing			*		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			nitted analytical record for product testing.		

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.\$.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
	0
	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.

1	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: Silodosin8mg		
	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 5 th 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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ for 24 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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 S	STUDY DATA

S.No Section Shortcoming Reply					
Damarka	temperature and humidity monitoring of stability chambers (real time and accelerated) marks of Evaluator:			and humidity monitoring ability chambers.	g of real time and
6.				ibmitted record of digi	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product		HPLC system		_
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			mitted analytical record fo	r product testing.
3.	Documents for the procurement of API with approval from DRAP (in case of import).		# TY120208 (Karachi) on 0 # 13001-2006	11238 dated: 11-08-2020 01-09-2020 specifying 100 503-2	cleared by DRAP og of Silodosin batch
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		issued by Chi		administration
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.		
	DOCUMENTS / DATA TO		1		
No. of Bat	tches			03	I
Date of In	-	26-04		26-04-2021	26-04-2021
Manufactu		04-2	_	04-2021	04-2021
Batch Size			Capsule	1500 Capsule	1500 Capsule
Frequency Batch No.			0, 3, 6 (Month , 3, 6 (Months)		TR-015-21
Time Perio	od	Real time: 6 1 Accelerated:			
Stability S	Storage Condition		$^{\circ}$ C ± $^{\circ}$ C / 65% 40° C ± $^{\circ}$ C / 7.		
Descriptio (Container	on of Pack r closure system)	Alu Alu foil			
API Lot N	lo.	13001-20060	3-2		
Manufacturer of API		ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. Address: No. 15, Donghai 5 th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.			

the manufacturing unit issued within the last three years shall be submitted. 2. 1.6.5 Valid Drug Manufacturing License or Valid Good Manufacturing License or Valid Drug Manufacturer is sued by relevant regulatory authority of country of origin submitted. 3. 2.5.4.1 Copies of the Drug substance specifications by Drug Product manufacturer is required. 4. 3.2.5.4.2 Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required. 5. 3.2.5.4.3 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted for not performing Uniformity of dosage units in pharmaceutical equivalence. 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 flasks and sampler valis. Justify the performance of analytical procedures wholl davoid exposure to light using brown volumetric flasks and sampler valis. Justify the performance of analytical procedures should avoid exposure to light using brown volumetric flask and sampler valis. Justify the performance of analytical procedures of soldosin 4mg and 8mg Capsules were performed in amber glassware for temperature and humidity monitoring of stability chambers (real time and accelerated) 8 Submitted. • Submitted. • Submitted. • Submitted. • Silodosin is a light sensitive material therefore the whole analytical procedures of soldosin 4mg and 8mg Capsules between the residence department of a whorter (Standard / samples from light). Revised opposite at th	1.	1.3.5	GMP inspection report/ GMP certificate of	Valid GMP certificate of the
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6. 3.2.P.2.2 Justification shall be submitted for not performing Uniformity of dosage units in pharmaceutical equivalence. 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. • 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 against innovator sample and revised Pharmaceutical equivalence submitted. • Submitted. • Silodosin is a light sensitive material therefore the whole analytical procedure should avoid exposure to light using brown volumetric flasks and other glassware without taking these precautions. (Testing of Silodosin 4mg and 8mg Capsules but due to typo error protection of standard / samples from light are missing in "Testing Procedures". 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)			by the Drug Product manufacturer drug	by the Drug Product manufacturer drug
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monitoring of stability chambers (real time and accelerated)				
(real time and accelerated)				•
				<u> </u>
submitted.				· ·
				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.

	n 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 Zinc20mg
	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,

			manufactu analytical and justif	s, physical form, manufaring process and corprocedures and its validation of specification closure system and stall	ntrols, specifications, dation, batch analysis, reference standard,
	Stability Studies of Drug Sub (Conditions & duration of St		Long term	udy conditions: : 30°C ± 2°C / 65% ± 5% d: 40°C ± 2°C / 75% ± 5	
	Module-III Drug Product:		description manufactu process v control o procedures analysis,	irm has submitted data of drug product including its escription, composition, pharmaceutical development, nanufacture, manufacturing process and process control, rocess validation protocols, control of excipients, ontrol of drug product, specifications, analytical rocedures, validation of analytical procedures, batch nalysis, justification of specifications, reference tandard or materials, container closure system and tability.	
	Pharmaceutical Equiva Comparative Dissolution Pro		product ag Pharmaceu ,Identificat	submitted pharmaceutical equivalence of their gainst the Osiris Syrup 20mg/5ml by Sami utical by performing quality tests (Description, tion, pH, Uniformity of dosage units, le volume, Assay,).	
	Analytical method validatio product	n/verification of		Firm has submitted analytical method verification study reports for drug product.	
	1	STABILITY S	•	0 1	
Manufact	urer of API	Rasina Herbs Po N-2, M.I.D/C. O		one, Kupwad, sangli.	
API Lot N	No.	ZnMop22004			
	on of Pack er closure system)	Amber glass bo	Amber glass bottle USP Type III		
Stability S	Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time Peri	iod	Real time: 6 months Accelerated: 6 months			
Frequency	y	Accelerated: 0, Real Time: 0, 3,			
Batch No		T-01		T-02	T-03
Batch Siz	e	45 bottl	es	45 bottles	45 bottles
Manufact	uring Date	09-202	21	09-2021	09-2021
Date of Ir	Date of Initiation		021	27-09-2021	27-09-2021
No. of Ba	No. of Batches			03	
DOCUMENTS / DATA TO BE PROVIDED A			ALONG W	TTH STABILITY STUI	DY DATA
1.	Reference of previous approval of applications with stability study data of the firm (if any)				
2.			No.6111495)	submitted copy of GMP issued by Food and Dru valid till 20-02-2024.	

3.	•	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.	
5.	*	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	6 66	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	Available In IP as solution (Available strength: 10mg & 20mg of zinc per 5ml)
		formulation in the same composition,	strength. Total & 20mg of Zaic per 3mi)
		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.	
2.	1.6.5	Valid Drug Manufacturing License or	Valid Good Manufacturing Practice
		Valid Good Manufacturing Practice	(GMP) certificate of the Drug Substance
		(GMP) certificate of the Drug Substance	manufacturer issued by relevant
		manufacturer issued by relevant regulatory authority of country of origin.	regulatory authority of country of origin submitted.
3.	2.3.R.1.1	Justify Quantity of zinc sulphate	1mg of elemental zinc is equivalent to
] 3.	2.3.10.1.1	dispensed in stability batches and how	2.745mg of Zinc Sulfate , 2.47mg
		1mg of zinc sulphate is equivalent to	mentioned by mistake
		2.470mg of elemental zinc.	, and the second
4.	3.2.S.4.1	Copies of the Drug substance	Submitted
		specifications by both Drug substance &	
_		Drug Product manufacturer is required.	
5.	3.2.S.4.2	Analytical procedures used for routine	Submitted
		testing of the Drug substance /Active	
		Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer	
		is required.	
6.	3.2.P.1	Provide reference of product	• We have selected most
		which is used for formulation in	commonly used excipients for
		terms of excipients as WHO	liquid dosage form. We have
		prequalified product (zinc	performed active-Excipient
		sulphate 10mg/5ml) is different	compatibility study.
		than your product in terms of	• 1mg of elemental zinc is
		formulation.	equivalent to 2.745mg of Zinc
		How 1mg of zinc sulphate is against to 2.470mg of	Sulfate, 2.47mg mentioned by
		equivalent to 2.470mg of elemental zinc justify your	mistake.
		quantity per 5ml with reference	

7.	3.2.P.5.3	[Zinc (as sulfate) 10 mg/5 mL oral solution]. Analytical method verification studies of drug substance and drug product are		
		same. Clarify how.		
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 Sodium50mg.
	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 regu	llatory authorities	Diclofenac Sodium 50mg enteric coated tablet, TEVA Pharmaceutical, MHRA Approved.
For generic drugs (me-too s	status)	Dicloran 50mg tablet, SAMI Pharmaceuticals Pvt Limited. Pakistan
Name and address of API n	nanufacturer.	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 Stability Studies of Stability Studies of Drug Stability Studies of Drug Stability Studies of Stabi		Stability study conditions: Long term: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ for 60 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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 Equi Comparative Dissolution P	valence and rofile	
Analytical method validation	on/verification of	Firm has submitted analytical method verification study reports for drug product.
	STABILITY S	TUDY DATA
Manufacturer of API		Pharmaceutical Production Zone of pharmaceutical factory, West Jishne y, 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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Peri	od		Real time: 6 a Accelerated:			
Frequency	ý			0, 3, 6 (Months)		
Batch No.	•		20TR	2n021	21TRn008	21TRn009
Batch Size	e		2000) tab	2000 tab	2000 tab
Manufact	uring Date		12-2	2020	06-2021	06-2021
Date of In	itiation		24-06	-2021	24-06-2021	24-06-2021
No. of Ba	tches				03	
	DOCUMEN	TS / DATA TO	BE PROVIDI	ED ALONG W	/ITH STABILITY STUD	Y DATA
1.		with stability stu	approval of ady data of the			
2.	API manufa		by concerned	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.				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 subr	mitted analytical record fo	r product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing					
6.	temperature	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and			ibmitted record of digital and humidity monitoring ability chambers.	
	of Evaluator					
	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 while we have used A same role in the form achieved satisfactory res and chemical attribute during product develop studies.	avicel 102 for the nulation and have sult for the physical s of the product	
3.	3.2.P.2.2.1	Submit complete Comparative dissolution profile. Complete comparative dissolution submitted.			ive dissolution	

 Reference of previous approval of applications with stability study data of the firm. Batch # 20TRn021 is in Decomposition in Decompositi	# 20TRn021 was dispensed s-2020, but batch was seed later, Coated tablets ested on 10 th June, 2021 and ty studies were started on ane, 2021.
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- 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)

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	
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

STABILITY STUDY DATA		
•	Firm has submitted analytical method validation study reports for drug product.	
	International Sarl. Istanbul Turkey performing quality tead Appearance, Dissolution, Assay. CDP has been performed against the 'Revlimid 5mg Capsules' Celgene International Sarl. Istanbul Turkey in Acidic media (p. 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values are in the acceptable range.	
Pharmaceutical Equivalence and Comparative	Firm has submitted pharmaceutical equivalence of their product against the product Revlimid 5mg Capsules by Celge	
	Firm has submitted data of drug product including its description composition, pharmaceutical development, manufacturing process and process control, process validation protocols, control of excipients, control of drug produst specifications, analytical procedures, validation of analytic procedures, batch analysis, justification of specifications, referent standard or materials, container closure system and stability.	
(Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of dr substance at both accelerated as well as real time conditions. To accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{I}$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} = 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 60 months.	
	Firm has submitted detailed data for drug substance data related nomenclature, structure, general properties, solubility's, physiform, manufacturers, description of manufacturing process a controls, impurities, specifications, analytical procedures and validation, batch analysis and justification of specification, referer standard, container closure system and stability studies of dr substance.	
	Firm has submitted QOS as per WHO QOS-PD template. Firm I summarized information related to nomenclature, structure, gene properties, solubilities, physical form, manufacturers, description manufacturing process and controls, impurities, specificatio analytical procedures and its validation, batch analysis a justification of specification, reference standard, container closs system and stability studies of drug substance and drug product.	
	M/S Hetero Labs Limited, Unit-I, Sy.No.10, I.D.A., Gaddapothar Village, Jinnaram Mandal, Sangareddy District, Pinco 502319, Telangana State, India	
For generic drugs (me-too status)	Relidomide 5mg Capsule of M/s M/s Helix Pharma	
•	REVLIMID by BRISTOL MYERS SQUIBB of (PMDA Approved)	
Proposed unit price	6,000/=	
Proposed Pack size	3 x 7's	
Reference to Finished product specifications	In-house specifications	
Pharmacotherapeutic Group of (API)	Film coated tablet	
Pharmaceutical form of applied drug	Other immunosuppressant's. ATC code: L04AX04.	

Manufacturer of API				d, Unit-I, Sy.No.10, I.D. ddy District,Pincode 5023	.A., Gaddapotharam Village, 19,Telangana State,India	
API Lot No.		LG22090001 LG22110002				
	ription of Pacl ainer closure		Alu-alu blister	•		
Stabil	ity Storage C	ondition		Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time	Period		Real time: 6 months Accelerated: 6 months			
Frequ	ency		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
Manu	facturing Dat	e	May-2023		May-2023	May-2023
Date	of Initiation		09-06-2023		09-06-2023	09-06-2023
No. o	f Batches				03	
	1		TO BE PROV	VIDED ALO	NG WITH STABILITY	STUDY DATA
1.	Reference application firm (if any	of previous s with stability stu	approval of ady data of the			
2.	API manı	of API/ DML/GMI ufacturer issued authority of country	by concerned	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.		for the procureme om DRAP (in case		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 su data sheets,		f testing of all batches, raw	
5.		e Record of Hi udit trail reports on			system is not 21 CFR com	pliant.
6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		of stability			lata logger for temperature and accelerated stability chambers.	
Evalu	ation by PE	C:				
	S.No	Shortcoming			Reply	
	1.	Evidence of approximate the same computed Lenalidomide as form in one of authority specifical The name of the mentioned as adoption.	of the applied for position, salt Hemihydrate the reference d by Registrate reference author	rmulation in form i.e., and dosage regulatory tion Board. rity shall be	Firm has referred to the for EMA Public assessment innovator drug product capsules for the describing substance i.e., Lenalidom "It is a synthetic derivative and is structurally clossed."	nt report of the et i.e., Revlimid ription of active nide.

		(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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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) & acceptable		.8). The f2 values are in the	
	Analytic	l			Firm has submitted analytical method validation study reports for as drug product.		
			STABI	LITY STUI	OY DATA		
Man	ufacturer o	of API			d, Unit-I, Sy.No.10, I.D. ddy District,Pincode 50231	A., Gaddapotharam Village, 9,Telangana State,India	
API	Lot No.		LG22090001 LG22110002				
	cription of ntainer clos	Pack sure system)	Alu-alu blister				
Stab	ility Storag	ge Condition	Real time: 30° Accelerated: 4				
Time	e Period		Real time: 6 m Accelerated: 6				
Freq	uency		Accelerated: 0 Real Time: 0,				
Batc	h No.		009N503-10		009N504-10	009N505-10	
Batc	h Size		2428 capsules		2428 capsules	2428 capsules	
Man	ufacturing	Date	May-2023		May-2023	May-2023	
Date	of Initiation	on	09-06-2023		09-06-2023	09-06-2023	
No.	of Batches				03		
	D	OCUMENTS / DAT	TA TO BE PROV	IDED ALC	NG WITH STABILITY	STUDY DATA	
1.	Reference applica firm (if	tions with stability s					
2.	API r		by concerned	DRUGS		No:91056/TS/2022 issued by RATION Government of alid until 29/09/2025.	
3.		Documents for the procurement of API with approval from DRAP (in case of import).		Clinical Tri 115615689 Commercia	al, Examination, Test Or A 4265, dated; 28-Oct-2022	nalysis) # K- 2227365 dated: 07-01-2023	
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 batch data sheets, COA and summary data sheets.						
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing			oliant.			
6.						ata logger for temperature and accelerated stability chambers.	
Eval	uation by				Donly		
	S.N 1.	Evidence of marketing status	approval / reg	mulation in	Firm has referred to the fo EMA Public assessmen	nt report of the	
		the same con	mposition, salt	form i.e.,	innovator drug produc	t 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		
	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
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{RH}$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{RH}$ for 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.				
		STABI	LITY STUDY DATA	
Manu	facturer of API		Labs Limited, Unit-I, Sy.No.10, I.D.A., Gadal, Sangareddy District, Pincode 502319, Tela	
API L	ot No.	LG22090001 LG22110002		
	ption of Pack hiner closure system)	Alu-alu blister		
Stabil	ity Storage Condition		$^{\circ}$ C ± $^{\circ}$ C / $^{\circ}$ 65% ± 5%RH $^{\circ}$ 0 $^{\circ}$ C ± $^{\circ}$ C / $^{\circ}$ 5% ± 5%RH	
Time	Period	Real time: 6 m Accelerated: 6		
Freque	ency	Accelerated: 0 Real Time: 0,	9, 3, 6 (Months) 3, 6 (Months)	
Batch	No.	009N503-25	009N504-25	009N505-25
Batch	Size	1450 Capsules	1450 Capsules	1450 Capsules
Manu	facturing Date	May-2023	May-2023	May-2023
Date of	of Initiation	13-06-2023	13-06-2023	13-06-2023
No. of	Batches		03	
	DOCUMENTS / DATA	A TO BE PROV	/IDED ALONG WITH STABILITY STUD	Y 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		1 **	ON Government of
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) I Clinical Trial, Examination, Test Or Analysis) # K- 1156156894265, dated; 28-Oct-2022 Commercial Invoice No # S13622227365 dated: 07-01-20 Ledolinmide batch # LG22090001 & LG22110002		s) # K- 55 dated: 07-01-2023	
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, raw data sheets, COA and summary data sheets.			g of all batches, raw
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing			
6.		of stability	Firm has submitted record of digital data logs humidity monitoring of real time and accelerate	
	1. Evidence of a marketing status of the same com Lenalidomide as form in one of authority specifi	of the applied for aposition, salt Hemihydrate af the reference	form i.e., and dosage regulatory regulatory EMA Public assessment report innovator drug product i.e., capsules for the description substance i.e., Lenalidomide.	ort of the Revlimid

	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.
	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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{RH}$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{RH}$ for 24 months.
	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
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.

1	Analytical method validation/verification of product Firm has submitted analytical method verification study reports for as drug product.			
		STABI	LITY STUDY DATA	
		aboratories PVT., Limited (UNITE-I) pakulagudem, Pochavaram panchayat Tallapud sh.	i, west Godavari, Dist.	
API Lo	ot No.	TBH00122		
	ption of Pack iner closure system)	Alu-Alu bliste	r	
Stabilit	ty Storage Condition		$^{\circ}$ C ± $^{\circ}$ C / $^{\circ}$ 65% ± 5% RH $^{\circ}$ 0 $^{\circ}$ C ± $^{\circ}$ C / $^{\circ}$ 75% ± 5% RH	
Time P	Period	Real time: 6 m Accelerated: 6		
Freque	ency	Accelerated: 0 Real Time: 0,	3, 6 (Months)	
Batch I	No.	T001	T002	T003
Batch S	Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufa	acturing Date	02-2023	02-2023	02-2023
Date of	f Initiation	20-02-2023	20-02-2023	20-02-2023
No. of	Batches		03	
	DOCUMENTS / DATA	A TO BE PROV	VIDED ALONG WITH STABILITY STUDY	Y DATA
1.	Reference of previous applications with stability stufirm (if any)	approval of udy data of the		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Copy of GMP certificate No# HMF07-1503 issued by DRUGS CONTROL ADMINISTRA Andhra Pradesh issued dated: 15/05/2023 valid COPY of DML No # 08/WG/AP/2019/B/CONTROL ADMINISTRATION Government Dated: 20-03-2019 and valid till 19-03-2024	ATION Government of id for one year. G issued by DRUGS
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Copy of form 5, [Drug Import License) No. K issued on 25/04/2022 by Drug Regulatory Au valid till 24/04/2024 specifying Terbinafine H Firm Submitted form 3, form 7 and Clearance 1051748776785 specifying # commercial Invested: 31-03-2022 specifying Terbinafine HC TBH00122.	thority of Pakistan, ICl was provided. certificate # E- oice # EXP/189/21-22
4.			Firm has submitted complete record of testing data sheets, COA and summary data sheets.	; of all batches, raw
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing			
6.			Firm has submitted record of digital data logg humidity monitoring of real time and accelera	
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.

- 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.

76. 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	
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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					
Sy No: 29 Tuj			aboratories PVT., Limited (UNITE-I) akulagudem, Pochavaram panchayat Tallap sh.	oudi, west Godavari, Dist.		
API Lo	ot No.		TBH00122			
	ption of P	ack re system)	Alu-Alu bliste	r		
Stabili	ty Storage	• Condition		me : 30°C ± 2°C / 65% ± 5%RH erated: 40°C ± 2°C / 75% ± 5%RH		
Time I	Period			Real time: 6 months Accelerated: 6 months		
Freque	ency		Accelerated: 0 Real Time: 0,	, 3, 6 (Months) 3, 6 (Months)		
Batch	No.		T004	T005	T006	
Batch	Size		1000 Tablets	1000 Tablets	1000 Tablets	
Manuf	facturing I	Date	02-2023	02-2023	02-2023	
Date o	f Initiation	1	21-02-2023	21-02-2023	21-02-2023	
No. of	Batches			03		
	DO	OCUMENTS /	DATA TO BE PROV	TIDED ALONG WITH STABILITY STU	DY DATA	
1.	Reference of previous approval of applications with stability study data of the firm (if any)					
2.	* *		sued by concerned	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. on 25/04/2022 by Drug Regulatory Author 24/04/2024 specifying Terbinafine HCl was Firm Submitted form 3, form 7 and Cl 1051748776785 specifying # commercial dated: 31-03-2022 specifying Terbinafin TBH00122.	rity of Pakistan, valid till s provided. earance certificate # E- Invoice # EXP/189/21-22	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		documents like data sheets, COA,	Firm has submitted complete record of test data sheets, COA and summary data sheets		
5.	Compliance Record of HPLC software Our HPLC system is not 2 21CFR & audit trail reports on product testing			Our HPLC system is not 21 CFR complian	t.	
6.	and hu		toring of stability	Firm has submitted record of digital data lo humidity monitoring of real time and accel-		
Evalua	ation by I	PEC:				
	S.No	Section	Shortcoming	Reply		
	1.	2.3.R.1.1	Provide copy Manufacturing Reco all the batches of dru which stability stu	ig product for		

2.	3.2.P.2.2.1	provided in Module 3 section 3.2.P.8.3 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. 	

- 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 HCl10.0mg		

	Pharmaceutical form of applied drug		Antifungal Agents
	Pharmacotherapeutic Group of (A	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 manuf	acturer.	M/s Tagoor Laboratories PVT., Limited (UNITE-I) Sy No: 29 Tupakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. Andhra Pradesh.
	Module-III (Quality Overall Summary) Module-III Drug Substance: Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile		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.
			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.
			Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months.
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
			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/v	verification of	Firm has submitted analytical method verification study reports for as drug product.
		STABI	LITY STUDY DATA
Manu	_		aboratories PVT., Limited (UNITE-I) pakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. sh.
API L	ot No.	TBH00122	
	Description of Pack Container closure system) Aluminium Tu		ıbe
Stabil	, ,		$^{\circ}$ C ± 2 $^{\circ}$ C / 65% ± 5%RH 0 $^{\circ}$ C ± 2 $^{\circ}$ C / 75% ± 5%RH

Time	e Period		Real time: 6 m Accelerated: 6				
Freq	uency		Accelerated: 0 Real Time: 0,				
Batc	h No.		T001		T002	T003	
Batch Size 500 Tubes		500 Tubes		500 Tubes	500 Tub	es	
Man	ufacturing	Date	03-2023		03-2023	03-202	3
Date	of Initiation	on	17-03-2023		17-03-2023	17-03-20)23
No.	of Batches				03	•	
	D	OCUMENTS	/ DATA TO BE PROV	IDED ALO	NG WITH STABILITY	STUDY DATA	
1.	Reference applica firm (if	tions with stal	evious approval of bility study data of the				
2.	API n	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		issued by DF Andhra Prad COPY of I CONTROL Dated: 20-03	RUGS CONTROL ADM esh issued dated: 15/05/2 DML No # 08/WG/AP/ ADMINISTRATION G 3-2019 and valid till 19-0	INISTRATION Govern 2023 valid for one year. 2019/B/G issued by l overnment of Andhra 03-2024	nment of DRUGS Pradesh
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 til 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.	attested	l respective	documents like data sheets, COA,	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.			
5.			of HPLC software eports on product testing	Our HPLC system is not 21 CFR compliant.			
6.	and h	numidity more		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers			
Eval	luation by		T a			1	
	2.	Section 2.3.R.1.1 3.2.S.4.4	Provide copy Manufacturing Rec for all the batches of 6 for which stability st provided in Module 3.2.P.8.3 Finished product is a specifications while substance USP speci applied. Justify.	drug product udies data is e 3 section pplied on JP e on drug	Reply Submitted The working standard p for trail batch was of U the applied product is Therefore as per preca	JSP specification. As on JP Specifications.	
			applica. Justily.		compare the COA of p Specification of terl material given in JP Ph them were found to be	rovided material with binafine HCL raw armacopeias .Both of	

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.

	Lotio	n 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 hydrochloride10.0mg
	Pharmaceutical form of applied drug	Antifungal Agents

	Pharmacotherapeutic Group of (API)	Colorless to pale yellow clear liquid	
	Reference to Finished product sp	ecifications	Innovator's Specs	
	Proposed Pack size		20ml, 30ml, 60ml	
	Proposed unit price		As per SRO	
	The status in reference regulator	y 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 manuf	acturer.	M/s Tagoor Laboratories PVT., Limited (UNITE-I) Sy No: 29 Tupakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. Andhra Pradesh.	
	Module-II (Quality Overall Sum	mary)	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 Substat (Conditions & duration of Stabil		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%RH$ RH for 6 months. The real time stability data is conducted at $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%RH$ 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.	
	product		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.	
			Firm has submitted analytical method verification study reports for as drug product.	
			LITY STUDY DATA	
Manu	nfacturer of API		aboratories PVT., Limited (UNITE-I) bakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. sh.	
API I	Lot No.	TBH00122		
	ription of Pack tainer closure system)	HDPE bottles		
Stabi	Stability Storage Condition Real time: 30°C		$^{\circ}$ C ± $^{\circ}$ C / $^{\circ}$ 65% ± 5%RH $^{\circ}$ C ± $^{\circ}$ C / $^{\circ}$ 75% ± 5%RH	

Time	Period		Real time: 6 m Accelerated: 6			
Frequ	ency		Accelerated: 0 Real Time: 0,), 3, 6 (Months) 3, 6 (Months)		
Batch No. TB01			TB02	TB03		
Batch	Size		500 Bottles		500 Bottles	500 Bottles
Manu	facturing	g Date	04-2023		04-2023	04-2023
Date	of Initiat	ion	13-04-2023		13-04-2023	13-04-2023
No. o	f Batche	S		I.	03	1
]	OOCUMENTS	/ DATA TO BE PROV	VIDED ALONG	WITH STABILITY S	TUDY DATA
1.	Refere applic firm (i	ations with stal	evious approval of bility study data of the			
2.	· · · · · · · · · · · · · · · · · · ·		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.	atteste	d respective	documents like data sheets, COA,	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.		
5.			of HPLC software eports on product testing	Our HPLC system is not 21 CFR compliant.		
6.	and		nitoring of stability	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Evalu	ation by	PEC:				
	S.No 1.	Section 1.5.6	solution is for cutane and JP Pharmacopeia specified that "Liquid for Cutaneous Application preparations intended to the skin (including Liniments and Lotions	erence product as use while in JP binafine HCl ous application general chapters and Solutions ation are liquid for application scalp) or nails. The are included in Justify your	Reply Our applied product te Innovator Specification studies were performed too product (Terebine Innovator specification Whereas Lamisil lotton RRA reference. In Netherland (RRA) solution for cutaneous while in JP Pharma HCl solution is for cutand JP Pharmacope specified that "Liquid	ons and comparative ed against local me esil) Which is on on and is a lotion. In was quoted only as Lamisil Lotion 1%, ous use mentioned. It was application to the estancous application will general chapter

			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

	T	2 Communication	1
S.No	Section	Shortcoming	Reply
1.	3.2.P.5.2 &	Applied label claim is 1gm	It is stated that the label claim of
	3.2.P.8	contains 10mg of Terbinafine	our applied product TERBIGEN
		HCl, while in Analytical testing	Lotion 1% w/w is as under
		method and stability studies raw	Each gm contains:
		data sheets 1ml is dispensed for	Terbinafine
		sample preparation. Clarify.	hydrochloride10.0mg
			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

ı	4	T 11 + /C 1
	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)
Name, address of Applicant / Marketin 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 fa	Firm has submitted copy of letter of grant of DML dated 29-04-202 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 na	ame TERBIPINE 1% CREAM
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Terbinafine hydrochloride1%w/w(10mg)
Pharmaceutical form of applied drug	Antifungal
Pharmacotherapeutic Group of (API)	White to off white colored cream
Reference to Finished product specification	ons JP Spec's
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authori	ties 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 manu	facturer.	M/s Tagoor Laboratories PVT., Limited (UN Sy No: 29 Tupakulagudem, Pochavaram pan Godavari, Dist. Andhra Pradesh.			
Module-II (Quality Overall Sur	nmary)	Firm has submitted QOS as per WHO QOS-summarized information related to nomencla properties, solubilities, physical form, manufacturing process and controls, impanalytical procedures and its validation, justification of specification, reference stand system and stability studies of drug substance.	acture, structure, general acturers, description of urities, specifications, batch analysis and dard, container closure		
Module-III Drug Substance:		Firm has submitted detailed data for drug substance data related nomenclature, structure, general properties, solubility's, phys form, manufacturers, description of manufacturing process controls, impurities, specifications, analytical procedures and validation, batch analysis and justification of specification, refere standard, container closure system and stability studies of disubstance.			
Stability Studies of Drug Substa (Conditions & duration of Stabi		substance at both accelerated as well as rea accelerated stability data is conducted at 40°C	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% + 5\%\text{RH}$ for 36 months		
Module-III Drug Product:	Module-III Drug Product:		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
Pharmaceutical Equivalence ar Dissolution Profile	nd Comparative	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. Firm has submitted analytical method verification study reports for as drug product.			
Analytical method validation product	verification of				
	STABI	LITY STUDY DATA			
Manufacturer of API		aboratories PVT., Limited (UNITE-I) bakulagudem, Pochavaram panchayat Tallapudi, west Godavari, Dist. sh.			
API Lot No.	TBH-0020421				
Description of Pack (Container closure system) Aluminium Tu		ube			
, ,		$^{\circ}$ C ± $^{\circ}$ C / $^{\circ}$ 65% ± 5%RH $^{\circ}$ C ± $^{\circ}$ C / $^{\circ}$ 75% ± 5%RH			
Time Period	Time Period Real time: 6 m Accelerated: 6				
Frequency	Accelerated: 0 Real Time: 0,), 3, 6 (Months) 3, 6 (Months)			
Batch No.	T001	T002	T003		
Batch Size 200 Tubes(10g)		200 Tubes(10g)	200 Tubes(10g)		

Manu	facturi	ng Date	05-2023		05-2023	05-2023
	of Initi		10-05-2023	1	0-05-2023	10-05-2023
No. of	f Batch	nes		03		
		DOCUMENT	TS / DATA TO BE PRO	VIDED ALONG V	VITH STABILITY STUD	Y DATA
1.						
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		issued by DRUGS Andhra Pradesh is COPY of DML CONTROL ADM	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).		panacea pharmace Firm has submitte dated; 02-08-2021 date: 08-09-2021	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.			Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.			
5.			rd of HPLC software reports on product testing	Audit trail report for product testing submitted.		
6.	and	humidity n			d record of digital data logging of real time and accelera	
Evalu	ation 1	by PEC:				
-	S.No	Section	Shortcoming		Reply	
	1.	3.2.S.4.1	Copies of the Drug subspecifications of the Dr /Active Pharmaceutical Drug Product manufact	ug substance Ingredient by	Copies of the Dr specifications of the I /Active Pharmaceutical Drug Product manufacture	Ingredient by
	2.	3.2.S.4.2	Analytical procedures utesting of the Drug substitution Pharmaceutical Ingrediction Product manufacturer is	sed for routine stance /Active ent by Drug	Analytical procedures u testing of the Drug su Pharmaceutical Ingredic Product manufacturer is su	sed for routine bstance /Active ent by Drug
	3.	3.2.S.4.3	Analytical Method Vincluding specificity, repeatability (methors) the manufacturer drug subsubmitted.	accuracy and nod precision) Drug Product	Analytical method verifications substance submitted.	ication of drug
	4.	3.2.S.4.4	Finished product is specifications while o USP specifications are	n drug substance	The JP and USP are recognized pharmacopeia standards for the quality, and consistency of pharmathey share many similaritis slight differences in specific or testing methods. The specifications the finished USP specifications for the	a's that provide purity, strength, accuticals. While les, there may be fic requirements refore, using JP ed product and

			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.

- 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

recordingly, this has applied for following products for constantiation by Brag 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	
	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 Lacosamide100mg				
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 an justification 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 it 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 drusubstance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{R}$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} + 2^{\circ}\text{C} / 65\% \pm 5\%$ 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 be 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 validat product	tion/verification of	Firm has submitted analytical method verification study reports for as drug product.		
		STABI	LITY STUDY DATA		
Man	ufacturer of API	_	Life Sciences Private Limited, Sy.No.888 &90 adal, Kamareddy Dist,	1, Jangampally Village,	
API	Lot No.	LE2210006			
	ription of Pack tainer closure system)	Alu-Alu Bliste	er		
Stabi	lity Storage Condition		$^{\circ}$ C ± 2 $^{\circ}$ C / 65% ± 5%RH 0 $^{\circ}$ C ± 2 $^{\circ}$ C / 75% ± 5%RH		
Time	e Period	Real time: 6 m Accelerated: 6			
Frequ	uency	Accelerated: 0 Real Time: 0,	3, 6 (Months)		
Batc	h No.	TTR046	TTR047	TTR048	
Batc	h Size	1008 (Tablet)	1008 (Tablet)	1008 (Tablet)	
Man	ufacturing Date	02-2023	02-2023	02-2023	
Date	of Initiation	15-02-2023	15-02-2023	15-02-2023	
No. o	of Batches		03	,	
	DOCUMENTS / DA	ATA TO BE PROV	IDED ALONG WITH STABILITY STUD	Y DATA	
1.	Reference of previous applications with stability firm (if any)				
2.	· ·	ed by concerned	Telangana dated: 15-11-2019 and valid till 14-11-2024		
3.	Documents for the procur approval from DRAP (in o		Copy of form 6, [License to Import Drug(s) f Examination, Test or Analysis no. K- K-1458 12/01/2023 by Drug Regulatory Authority of valid till 11/01/2025 specifying LACOSAMI Firm has submitted copy of form 3, form 7 at # 22-23/U-1/E-030, dated; 23-12-2023 not c specifying 1.5Kg of Lacosamide batch # LE2	3307553412 issued on Pakistan, Karachi DE was provided. and Commercial Invoice leared by DRAP	
4.	Data of stability batches vattested respective chromatograms, Raw dasummary data sheets etc.	documents like	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.		
5.	Compliance Record of 21CFR & audit trail report		Audit trail report for product testing submitted.		
6.		ring of stability	Firm has submitted record of digital data log humidity monitoring of real time and accelerate		
Eval	uation by PEC:				
	1. 2.3.R.1.1 Pr	hortcoming rovide copy of fanufacturing Record rall the batches	rd (BMR) (BMR) for all the batches of dr	•	

		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
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 Img/ml but in	
10.	3.2.P.6	COA of primary / secondary	performance concentration for 100 % in accuracy and precision is 0.02mg/ml which is different from their method.	
10.	3.2.P.0	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.

<u> </u>	osi monograph wine performing the verification statutes 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	and the manner of the decre (confidence)					
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 17-09-202 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: Lacosamide50mg					
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 sp	necifications	USP		
Proposed Pack size		14's		
Proposed unit price		As per SRO		
The status in reference regulator	y 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 manuf	acturer.	M/s Raghava Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,		
Module-II (Quality Overall Sum	mary)	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 Substate (Conditions & duration of Stabil		Firm has submitted stability study data of 3 batches of drusubstance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{R}$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} + 2^{\circ}\text{C} / 65\% \pm 5\%$ 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 Dissolution Profile	d Comparative	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/v	verification of	Firm has submitted analytical method verification study reports for as drug product.		
	STABI	LITY STUDY DATA		
Manufacturer of API		Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, adal, Kamareddy Dist,		
API Lot No.	LE2210006			
Description of Pack Container closure system)	Alu-Alu Bliste	er		

Stability Storage Condition			Real time: 30 Accelerated: 4				
Time Period Real time: 6 m Accelerated: 6							
				0, 3, 6 (Months) , 3, 6 (Months)			
Batch	ı No.		TTR043		TTR044	TTR045	
Batch	n Size		1008 (Tablet)		1008 (Tablet)	1008 (Tablet)	
Manu	ıfacturing D	ate	02-2023		02-2023	02-2023	
Date	of Initiation	1	14-02-2023		14-02-2023	14-02-2023	
No. o	f Batches				03		
	DO	CUMENTS	/ DATA TO BE PROV	VIDED AL	ONG WITH STABILITY STUDY	DATA	
1.	firm (if a	ons with stat	evious approval of oility study data of the				
2.	API ma	nufacturer	ML/GMP certificate of issued by concerned f country of origin.	DRUGS	DML (form 25) No # TS/KRY/20 CONTROL ADMINISTRATION dated: 15-11-2019 and valid till 14-	N Government of	
3.			ocurement of API with (in case of import).	Firm has submitted copy of form 7 and Commercial Invoice # 22-23/U-1/E-030, dated; 23-12-2023 not cleared by DRAP specifying 1.5Kg of Lacosamide batch # LE2210006			
4.	attested chromato	respective	documents like data sheets, COA,	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.			
5.			of HPLC software ports on product testing		report for product testing submitted		
6.	and hu	midity mor			ubmitted record of digital data logge nonitoring of real time and accelerate		
Evalı	ation by P	EC:					
	S.No	Section	Shortcoming		Reply		
	1.	2.3.R.1.1	Manufacturing Recording for all the batches product for which studies data is producted as section 3.2.	of drug stability ovided in P.8.3	(BMR) for all the batches of drug for witch stability study data is pro attached.	g products ovided are	
	2.	3.2.S.4.1	Copies of the Drug su specifications of the I substance /Active Pharmaceutical Ingred Drug Product manufa required.	Orug dient by	Specifications of the drug substar pharmaceutical ingredient by dru manufacturer is attached.		
	required. 3. 3.2.S.4.2 Analytical procedures routine testing of the D substance /Active Pharmaceutical Ingredict Drug Product manufact required.		Drug dient by	Analytical procedure used for route of drug substance /Active pharringredient by drug product manufattached. Firm claimed Ph. Eur while method is as per USP monograp	naceutical facturer is submitted		

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.	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. Analytical method verification studies including specificity, accuracy and repeatability (method precision) of drug substance performed by the drug product manufacturer.
		shan be sublineed.	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.

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				
GMP status of the firm				
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 17-09-20 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 Tracking Id: X7G-YX1-D7VW Application No. 1520 dated 12-02 2024			
Dy. No. and date of submission				
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 Contact Lacosamide150mg			
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 &9 Jangampally Village, Bhiknoor Mandal, Kamareddy Dist,			
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm			

			properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closur system and stability studies of drug substance and drug product.			
	Module-III Drug Substance:		Firm has submitted detailed data for drug substance data related nomenclature, structure, general properties, solubility's, physician, manufacturers, description of manufacturing process a controls, impurities, specifications, analytical procedures and validation, batch analysis and justification of specification, referensiandard, container closure system and stability studies of dissubstance.			
	Stability Studies of Drug Subst (Conditions & duration of Stab		Firm has submitted stability study data of substance at both accelerated as well as real accelerated stability data is conducted at 40° C RH for 6 months. The real time stability data 2° C / $65\% \pm 5\%$ RH for 12 months.	If time conditions. The $C \pm 2^{\circ}C / 75\% \pm 5\%$ 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 a Dissolution Profile	nd Comparative	Firm has submitted pharmaceutical equival against the LACOLEP 150mg of Hilton performing quality tests Physical appear Disintegration time, Uniformity of do Dissolution) CDP has been performed against the 'LACO Pharma Pakistan in Acidic media (pH 1.2), A& Phosphate Buffer (pH 6.8). The f2 value range.	Pharma Pakistan by arance, Identification, sage units, , Assay, DLEP 150mg of Hilton Acetate Buffer (pH 4.5)		
	Analytical method validation product	/verification of	Firm has submitted analytical method verific as drug product.	cation study reports for		
		STABI	LITY STUDY DATA			
Manu	nfacturer of API		Life Sciences Private Limited, Sy.No.888 &901, Jangampally Village, idal, Kamareddy Dist,			
API I	Lot No.	LE2210006				
	ription of Pack tainer closure system)	Alu-Alu Bliste	er			
, ,			$0^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Period Real time: 6 m Accelerated: 6						
Frequ	lency	Accelerated: 0 Real Time: 0,	0, 3, 6 (Months) 3, 6 (Months)			
Batch	ı No.	TTR049	TTR050	TTR051		
Batch	ı Size	1008 (Tablet)	1008 (Tablet)	1008 (Tablet)		
Manufacturing Date 02-2023			02-2023	02-2023		

Date of Initiation 15-0		15-02-2023		14-02-2023	14-02-2023	
No. of Batches				03		
	DO	CUMENTS A	DATA TO BE PROV	VIDED AL	ONG WITH STABILITY STUD	Y DATA
a	Reference of previous approval of applications with stability study data of the firm (if any)					
A	API mai	nufacturer i	IL/GMP certificate of ssued by concerned country of origin.	DRUGS	DML (form 25) No # TS/KRY/CONTROL ADMINISTRATION dated: 15-11-2019 and valid till 14	ON Government of
			curement of API with in case of import).	23/U-l/E-0	ubmitted copy of form 7 and Comi 30, dated; 23-12-2023 not cleared acosamide batch # LE2210006	
a	ittested hromato	respective	documents like data sheets, COA,	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.		
			of HPLC software ports on product testing		report for product testing submitte	d.
a	ınd hur	midity mon	logger for temperature itoring of stability d accelerated)	Firm has so humidity n	ubmitted record of digital data loggnonitoring of real time and accelerate	ger for temperature and ated stability chambers.
Evaluati			,			
	S.No	Section	Shortcoming		Reply	
	1.	2.3.R.1.1	Provide copy of Manufacturing Recorder all the batches product for which studies data is product 3 section 3.2.	of drug stability ovided in	The copy of batch manufacture (BMR) for all the batches of dress for witch stability study data is pattached.	ug products
	2.	3.2.S.4.1	Copies of the Drug su specifications of the I substance /Active Pharmaceutical Ingree Drug Product manufa required.	ibstance Orug dient by	Specifications of the drug substantial pharmaceutical ingredient by drug manufacturer is attached.	rug product
	3.	3.2.S.4.2	Analytical procedures routine testing of the substance /Active Pharmaceutical Ingred Drug Product manufarequired.	Drug dient by	Analytical procedure used for rou of drug substance /Active pha ingredient by drug product man attached. Firm claimed Ph. Eur while method is as per USP monograproduct also Detection is at 215 used for drug product (tablet) substance Detection is at 2 concentration of standard as preparation are change from pha	rmaceutical ufacturer is submitted aph of drug m which is while drug 258nm and nd sample
	4.	3.2.S.4.3	Analytical Method V studies including s accuracy and re (method precision) by the Drug	specificity, peatability	Analytical method verification including specificity, accurrepeatability (method precision substance performed by the dramanufacturer.	on studies racy and n) of drug

		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 282^{nd} meeting held on 31^{st} 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

rdingly, firm has applied for following products for consideration by Drug Registration Board		
Oral Liquid Syrup Section (General)		
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, spe- procedures and its validation, batch analyst specification, reference standard, container stability studies of drug substance and drug pro-	is and justification of closure system and	
		Firm has submitted detailed data for drug suinomenclature, structure, general properties, form, manufacturers, description of manufacturers, impurities, specifications, analytic validation, batch analysis and justification of standard, container closure system and statsubstance.	solubility's, physical facturing process and al procedures and its specification, reference	
Stability Studies of Drug Substa (Conditions & duration of Stabi		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.		
Module-III Drug Product:		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
Pharmaceutical Equivalence ar Dissolution Profile	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 product	verification of	Firm has submitted analytical method verification study reports for as drug product.		
	STABI	LITY STUDY DATA		
Manufacturer of API		Life Sciences Private Limited, Sy.No.888 &901 adal, Kamareddy Dist,	, Jangampally Village,	
API Lot No.	AOND-22006			
Description of Pack (Container closure system)	Amber glass b	pottle + Aluminium cap		
Stability Storage Condition		${}^{\circ}\text{C} \pm 2 {}^{\circ}\text{C} / 65\% \pm 5\% \text{RH}$ $40 {}^{\circ}\text{C} \pm 2 {}^{\circ}\text{C} / 75\% \pm 5\% \text{RH}$		
Time Period	Real time: 6 m Accelerated: 6			
Frequency Accelerated: 0 Real Time: 0,		0, 3, 6 (Months) 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	A TO BE PROV	VIDED ALONG WITH STABILITY STUDY	Y DATA	

1.	app	erence dications n (if any	•	s approval of study data of the			
2.	API manufacturer issued by concerned		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).				and DeMont Res Firm has submitt 486022802639 of 2278922801827, 11 dated: 03-08-2	API's Loan between M/s World Biz Pharm earch Laboratories submitted. ed copy of form 5 (Drug Import License) lated: 07-06-2022 and Clearance certifical dated; 17-08-2022 specifying Invoice No 2022 Ondansetron hydrochloride batch #. Research Laboratories)	No# K- te # E- o # EXP-
4.			Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.		es, raw		
5.				HPLC software on product testing	Audit trail report	for product testing submitted.	
6.	Record of Digital data logger for temperature			ng of stability	Firm has submitt humidity monitor	ed record of digital data logger for temper ring of real time and accelerated stability of	rature and chambers.
Evalu	ation	by PEC	:				
		S.No	Section	Shortcoming		Reply	
		1.	3.2.S.4.4	Specification claims 3.2.S.4.1 are USI BP specification and drug product Clarification is reconspecifications and drug substance by manufacturer.	P while in COA are mentioned by manufacturer. quired that which the followed for by drug product	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	to be performendations pharmacopoeia) si	med as per of hall be provided.	Preservative effectiveness studies are attached.	
		3.	3.2.P.2.1.1	Compatibility students Substance(s) with the provided as composition of the not similar to innormal product.	n Glycerin shall the qualitative ne formulation is	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 Glycerin for DEC 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 3 rd 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) Eve Ointment (General)

2) Eye Ontment (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 / Track of submission	ing ID & date	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 Pharmaceutical ingredient (API)		Each gm contains: Acyclovir		
Pharmacotherapeutic Group of (A	API)	Antiviral		
Reference to Finished product spe	ecifications	BP		
	EVAL	UATION OF DATA		
GMP status of the firm	New DML iss	ued dated: 08-11-2022		
• •		mitted copy of Issuance of DML letter dated 08-11-2022 specifying t (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 modu	ile 3.2.S.			
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug s IV-A conditions.	substance as	per zone		
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 proc Eye Ointment of Remington Pharmaceutical	luct against t	he Lovir		
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	quency 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	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., LtdChina 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	USP is mistakenly written. We
		while product is not available in	have applied on BP specifications.
		USP Pharmacopeia.	
2.	1.6.5	Valid Drug Manufacturing License	Valid Drug Manufacturing License
		or Valid Good Manufacturing	or Valid Good Manufacturing
		Practice (GMP) certificate of the	Practice (GMP) certificate of the
		Drug Substance manufacturer	Drug Substance manufacturer
		issued by relevant regulatory authority of country of origin.	issued by relevant regulatory authority of country of origin
		authority of country of origin.	submitted.
3.	3.2.S.4.2	Analytical procedures used for	Analytical procedures used for
		routine testing of the Drug	routine testing of the Drug
		substance /Active Pharmaceutical	substance /Active Pharmaceutical
		Ingredient by Drug Product	Ingredient by Drug Product
		manufacturer is required	manufacturer are submitted.
4.	3.2.S.4.3	Analytical Method Verification	Analytical Method Verification
		studies including specificity,	studies including specificity,
		accuracy and repeatability	accuracy and repeatability
		(method precision) performed by	(method precision) performed by
		the Drug Product manufacturer for drug substance(s) shall be	the Drug Product manufacturer for drug substance is submitted.
		submitted.	drug substance is submitted.
5.	3.2.P,5.2	Detailed analytical procedures	Detailed analytical procedures
		used for testing the drug product	used for testing of the drug
		shall be provided.	product are submitted.
6.	3.2.P.5.3	Submit analytical method	Analytical method verification
		verification report	report is submitted.
7.	3.2.P.6	COA of primary / secondary	COA of primary / secondary
		reference standard including	reference standard is submitted.
		source and lot number shall be	
0	2200	provided.	D (6.4)
8.	3.2.P.8	Documents for the procurement of	Documents for the procurement of
		API with approval from DRAP	API are submitted.
		and agreement for loan of material.	
		material.	

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.

	registration application.			
185			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	
	Application Form Dy. No / Tracking ID & date of submission		☑ Manufacturer☐ Importer☐ Is involved in none of the above (contract giver)	
			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	
	Pharmacotherapeutic Group of (A	API)	Antibiotic and Steroid	
	Reference to Finished product sp	ecifications	USP Specifications	
		EVAL	UATION OF DATA	
GMI	GMP status of the firm New DML iss		ued dated: 08-11-2022	
	ence of approval of ufacturing facility		mitted copy of Issuance of DML letter dated 08-11-2022 specifying t (General) Section	
Prop	osed Pack size	3.5 gm		
Prop	osed unit price	As per SRO		
	status in reference regulatory orities	TobraDex Oin	ntment by Novartis Pharmaceuticals of (USFDA Approved)	
For g	generic drugs (me-too status)	Santodex Eye	Ointmen by Sante Private Limited	
	manufacturer. people Reput Dexamethas		ne: Zhejiang Xianju Pharmaceutical Co., Ltd xi Road, Modern Industrial Park, Xianju,	
	Module-II (Quality Overall Firm has subm Summary)		nitted QOS as per WHO QOS-PD template.	
Mod	Module-III Drug Substance: Firm has subm		nitted detailed drug substance data as per module 3.2.S.	
(Con	(Conditions & duration of Stability studies) as per zone IV Dexamethasor		Firm has submitted stability study data of 3 batches of drug substance 7-A conditions. ne: Firm has submitted stability study data of 3 batches of drug 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 STUD	Y 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	Inspection report is attached.
		steroids.	
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	Revised COA is submitted.
٥.	3.2.0.4.4	expiry on 05-11-2022 than how testing on 16-11-2022 can be conducted.	Revised COTT 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.

- 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 2024		Tracking Id: 1MQ-7LP-DQ9D Application No. 1463 dated 21-02-		
	Details of fee submitted	PKR 30,000/- : Deposit slip # 469610975487		

	The proposed proprietary name / brand name		SURGITOB-D EYE DROP (0.3 % Tobramy 0.1% Dexamethasone Ophthalmic Suspension		
	Strength / concentration of drug of Active		Each ml contains:		
	Pharmaceutical ingredient (API) per unit		Tobramycin		
	Pharmacotherapeutic Group of (API)	Antibiotic and Steroid		
	Reference to Finished product sp	pecifications	USP Specifications		
		EVAL	LUATION OF DATA		
GM	P status of the firm	New DML iss	sued dated: 08-11-2022		
	lence of approval of ufacturing facility		mitted copy of Issuance of DML letter dated General) Section	08-11-2022	specifying
Prop	oosed Pack size	5ml			
Prop	oosed unit price	As per SRO			
	status in reference regulatory orities	TobraDex oph Approved)	nthalmic suspension by Novartis Pharmaceutic	als of (USF	DA
For	generic drugs (me-too status)	TobraDex Eye	e Drop by NOVARTIS Pharmaceutical		
Name and address of API manufacturer. Tobramyc people Rep Dexametha 15 West Fe		people Repub Dexamethaso	one: Zhejiang Xianju Pharmaceutical Co., Ltd xi Road, Modern Industrial Park, Xianju,	.td.BeiBei, C	hongQing
	lule-II (Quality Overall mary)	Firm has subn	nitted QOS as per WHO QOS-PD template.		
Mod	lule-III Drug Substance:	Firm has subn	nitted detailed drug substance data as per mod	ule 3.2.S.	
	ility Studies of Drug Substance aditions & duration of Stability ies)	as per zone IV	Firm has submitted stability study data of 3 ba V-A conditions. Dexamethasone: Firm has sub- thes of drug substance as per zone IV-A condit	mitted stabilit	
Mod	lule-III Drug Product:	Firm has subn	nitted data of drug product as per module 3.2.I	P.	
Pharmaceutical Equivalence and Firm has submitted pharmaceutical ed			nitted pharmaceutical equivalence of their product of their production of Novartis PHARMACI RIES.		he
	lytical method lation/verification of product				
		STABI	LITY STUDY DATA		
API	Lot No.	Tobramycin: (Dexamethasor	08191203-U ne: X5-161102		
	Description of Pack (Container closure system) HDPE bottle				
Stab	tability Storage Condition Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$				
Time Period Real time: 6 m Accelerated: 6					
Freq	Frequency Accelerated: 0 Real Time: 0,), 3, 6 (Months) 3, 6 (Months)		
Batc	h No.	TMO-TRIAL	001	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 STUD	Y 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	Inspection report is attached.
		booths for steroids.	
2.	3.2.S.4.3	Analytical Method Verification	Analytical Method Verification
		studies including specificity, accuracy	studies including specificity, accuracy
		and repeatability (method precision)	and repeatability (method precision)
		performed by the Drug Product	performed by the Drug Product
		manufacturer both drug substance(s)	manufacturer for both drug
		shall be submitted for both	substance(s) Tobramycin and
_		Tobramycin and dexamethasone.	dexamethasone is submitted.
3.	3.2.S.4.4	Submitted COA of Dexamethasone	Revised COA is submitted.
		show expiry on 05-11-2022 than how	
		testing on 16-11-2022 can be	
4	2271	conducted.	
4.	3.2.P.1	Innovator product add Sulfuric acid/	Sodium hydroxide is used to adjust
		or Sodium hydroxide to adjust pH	the pH and evident from batch
		while in your formulation these are	manufacturing record.
5.	3.2.P.5.2	not included than how pH is adjusted.	Detailed analytical and advance your
5.	3.2.P.3.2	Detailed analytical procedures used for testing the drug product shall be	Detailed analytical procedures used
		provided.	for testing of the drug product are submitted.
6.	3.2.P.5.3	Submit analytical method verification	Analytical method verification report
0.	3.2.1 .3.3	report	is submitted.
7.	3.2.P.6	COA of primary / secondary	COA of primary / secondary
' '	3.2.1 .0	reference standard including source	reference standard for both
		and lot number shall be provided for	Tobramycin and dexamethasone are
		both Tobramycin and	submitted.
		dexamethasone.	
8.	3.2.P.8	Documents for the procurement of	Documents for the procurement of
		API with approval from DRAP and	API is submitted.
		agreement for loan of material for	
		dexamethasone	

- 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.

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)	

Pharmaceutical ingredient (API) per unit		Each ml contains: Polyethylene Glycol 400 4 mg Propylene Glycol				
Pharmacotherapeutic Group of (Pharmacotherapeutic Group of (API)		Lubricant Eye Drops			
	Reference to Finished product specifications					
	EVAL	UATION OF DATA				
GMP status of the firm	New DML iss	aued dated: 08-11-2022				
Evidence of approval of manufacturing facility		mitted copy of Issuance of DML letter dated General) Section	08-11-2022	specifying		
Proposed Pack size	15ml					
Proposed unit price	As per SRO					
The status in reference regulatory authorities	SYSTANE LUUSFDA)	UBRICANT by Alcon Laboratories, Inc of (OTC product	in		
For generic drugs (me-too status)	Systane by M/	/s Alcon Laboratories, Inc.Reg # 044834				
Name and address of API manufacturer.	Road, Kenli D Polyethylene	E GLYCOL: Shandong Shida Shenghua Ch District, Dongying City, Shandong-China glycol: Anhui Eapearl Chemical Co.Ltd. E ag City, Anhui Province CHINA				
Module-II (Quality Overall Summary)	Firm has subn	nitted QOS as per WHO QOS-PD template.				
Module-III Drug Substance:						
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:						
Pharmaceutical Equivalence and Comparative Dissolution Profile		nitted pharmaceutical equivalence of their production Manufactured by Alcon Labora		he		
Analytical method validation/verification of product						
	STABI	LITY STUDY DATA				
API Lot No.	Propylene Gly Polyethylene G	vcol: Glycol 400 : EP20230414H				
Description of Pack (Container closure system)	HDPE bottle					
Stability Storage Condition	Stability Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$					
Time Period	Real time: 6 months Accelerated: 6 months					
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)					
Batch No. SYS-TRIAL00		01	SYS- TRIAL002	SYS- TRIAL003		
Batch Size 15 L (1000 P		acks)	15 L (1000 Packs)	15 L (1000 Packs)		
Manufacturing Date	11-2022		11-2022	11-2022		
<u>U</u>	1		I .	1		

Date of Initiation			
No. of Batches	03		
DOCUMENTS / DATA	TO BE PROVIDED ALONG WITH STABILITY STUD	Y 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. ☑ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)		
	Status of the applicant			
	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 Cholecalciferol50,000 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 mar	ufacturing process and o	controls, specifications,
				cal procedures and its va stification of specification	
			contain	ner closure system and s	
	Module-III Drug Substance:			nce and drug product.	g substance data related
			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.		general properties, nufacturers, description controls, specifications, didation, batch analysis on, reference standard,
	Stability Studies of Drug Subs (Conditions & duration of Sta		Long t	ty study conditions: erm: $5^{\circ}C \pm 2^{\circ}C \%$ for 36 erated: $25^{\circ}C \pm 2^{\circ}C / 60\%$	months ± 5% for 6 months
	Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. 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 product	n/verification of	Firm has submitted analytical method verification study reports for drug product.		
		STABILITY S'	TUDY I	DATA	
Manufac	cturer 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	2		
	tion of Pack ner closure system)	Alu-Pvdc Bliste	Alu-Pvdc Blister		
Stability	Stability Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Period		Real time: 6 months Accelerated: 6 months			
Frequen	Frequency		3, 6 (Mo	-	
Batch N	0.	TF-01		TF-02	TF-03
Batch Si	ize	1000 Capsi	ule	1000 Capsule	1000 Capsule
Manufac	Manufacturing Date			12-2022	12-2022
Date of	Initiation	12-2022		12-2022	12-2022
No. of Batches				03	

	DOCUMENTS / DATA TO BE PROVIDE	D 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.	*	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	temperature and humidity monitoring of	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 Pharmacopo 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.

- 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.

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: Cholecalciferol100,000 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,		

		T		
		and just	tification of specificati	alidation, batch analysis on, reference standard, stability studies of drug
Module-III Drug Substanc	e:	to no solubili of man analytic and jus	menclature, structure, ty's, physical form, ma ufacturing process and cal procedures and its va tification of specification er closure system and s	ag substance data related general properties, nufacturers, description controls, specifications, alidation, batch analysis on, reference standard, stability studies of drug
Stability Studies of Drug S (Conditions & duration of		Long te	y study conditions: orm: $5^{\circ}C \pm 2^{\circ}C \%$ for 36° rated: $25^{\circ}C \pm 2^{\circ}C / 60\%$	
Module-III Drug Product:		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
Pharmaceutical Equivalen Dissolution Profile	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 valida product	ntion/verification of	Firm has submitted analytical method verification study reports for drug product.		
	STABILITY S'	TUDY DATA		
Manufacturer of API	M/s Fermenta I Plot No. Z-109 Bharuch Gujrat	B & C,	SEZ-II., Dahej, Tal-Vaş	gra, City Dahej, District
API Lot No.	CLC0420170			
Description of Pack (Container closure system)	Alu-Pvdc Bliste	er		
Stability Storage Condition		$C \pm 2^{\circ}C / 65\% \pm 5\% RH$ $0^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\% RH$		
Time Period Real time: 6 mg Accelerated: 6				
Frequency Accelerated: 0, Real Time: 0, 3				
Batch No.	TF-01		TF-02	TF-03
Batch Size	1000 Caps	ule	1000 Capsule	1000 Capsule
Manufacturing Date	01-2023	3	01-2023	01-2023
Date of Initiation	01-2023	3	01-2023	01-2023
No. of Batches			03	
DOCUMENTS / DATA	TO BE PROVIDED A	ALONG	WITH STABILITY ST	TUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	* *	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.	
5.	*	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	temperature and humidity monitoring of	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.\$.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	☐ Generic Drug Product (GDP) ☐ 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: Cholecalciferol20,000 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:		to no solubil of man analyti and ju	ity's, physical form, manufacturing process and ocal procedures and its vastification of specification of specification of specification of specification of specification of specifications.	general properties, nufacturers, description controls, specifications, alidation, batch analysis on, reference standard,
Stability Studies of Drug Subs (Conditions & duration of Stab Module-III Drug Product:			Long t	ty study conditions: erm: $5^{\circ}C \pm 2^{\circ}C \%$ for 36 rated: $25^{\circ}C \pm 2^{\circ}C / 60\%$	
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
	Pharmaceutical Equivalence a Dissolution Profile	nd Comparative	against Theran	aceutical Equivalence la the Lundeos soft Gelat nex Healthcare Spain Physical appearance, colo	tin capsule 20000IU of by performing quality
	Analytical method validation product	verification of	Firm has submitted analytical method verification study reports for drug product.		
		STABILITY ST			
Manufac	cturer of API	M/s Fermenta E Plot No. Z-109 Bharuch Gujrat	B & C, SEZ-II., Dahej, Tal-Vagra, City Dahej, District		
API Lot	No.	CLC0420170			
	ion of Pack ner closure system)	Alu-Pvdc Bliste	er		
Stability	Storage Condition		al time: 30°C ± 2°C / 65% ± 5%RH celerated: 40°C ± 2°C / 75% ± 5%RH		
Time Pe	riod	Real time: 6 months Accelerated: 6 months			
Frequen	су	Accelerated: 0, Real Time: 0, 3			
Batch No	0.	TF-01		TF-02	TF-03
Batch Si	ze	1000 Capsu	ıle	1000 Capsule	1000 Capsule
Manufac	Manufacturing Date 01-202			01-2023	01-2023
Date of 1	Initiation	01-202	.3	01-2023	01-2023
No. of B				03	
	DOCUMENTS / DATA TO E	BE PROVIDED A	ALONG	WITH STABILITY ST	UDY DATA
1. Reference of previous approval of applications with stability study data of the firm (if any)					

2.	* *	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.		Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	temperature and humidity monitoring of	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	Copy of BMR is submitted.
		data is provided in Module 3 section 3.2.P.8.3	
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.

- 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.

, 11	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: Cholecalciferol25,000 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

				stification of specificationer closure system and since.	
	Stability Studies of Drug Subst (Conditions & duration of Stab		Stability study conditions: Long term: $5^{\circ}C \pm 2^{\circ}C$ % for 36 months Accelerated: $25^{\circ}C \pm 2^{\circ}C$ / $60\% \pm 5\%$ for 6 months		
			descripted develor process excipied analytic proceds specific	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
	Pharmaceutical Equivalence as Dissolution Profile	nd Comparative	agains manuf	aceutical Equivalence t the Banferol soft Gel actured by Angelini Phar tests (Physical appearan	atin capsule 250000IU ma spain by performing
	Analytical method validation product	/verification of		has submitted analytic reports for drug product.	al method verification
		STABILITY S	TUDY I	DATA	
Manufac	turer 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			
	ion of Pack er closure system)	Alu-Pvdc Blist	er		
Stability	Storage Condition	Real time: 30°C Accelerated: 40		65% ± 5%RH C / 75% ± 5%RH	
Time Per	riod	Real time: 6 months Accelerated: 6 months			
Frequenc	су	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No	0.	TF-01		TF-02	TF-03
Batch Siz	ze	1000 Caps	ule	1000 Capsule	1000 Capsule
	turing Date	01-2023	3	01-2023	01-2023
Date of I	nitiation	01-2023	3	01-2023	01-2023
No. of B				03	
	DOCUMENTS / DATA TO BE PROVIDED		ALONG	WITH STABILITY ST	UDY DATA
1.	Reference of previous a applications with stability stud firm (if any)	approval of ly data of the			
2.	Approval of API/ DML/GMP certificate of FAPI manufacturer issued by concerned fregulatory authority of country of origin.		irm (No. Administ	also submitted copy of C 23074378) issued by Fo ration Gujrat State India valid till 04-07-2026.	od & Drug Control

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.	*	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	temperature and humidity monitoring of	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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.

- 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: Cholecalciferol1,000 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

			contair substar		stability studies of drug
	(Conditions & duration of Stability studies) Module-III Drug Product:		Long to	Stability study conditions: Long term: 5°C ± 2°C % for 36 months Accelerated: 25°C ± 2°C / 60% ± 5% for 6 months Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
			descrip develo process excipie analyti proced specifi		
	Pharmaceutical Equivalence a Dissolution Profile	nd Comparative	against manufa	the Lundeos soft G	have been established delatin capsule 1000IU K by performing quality our, Assay)
	Analytical method validation product	/verification of		nas submitted analytic eports for drug product.	al method verification
		STABILITY S	TUDY I	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 Bl		Alu-Pvdc Blist	er		
Stability	Storage Condition	Real time: 30°C Accelerated: 40		65% ± 5%RH C / 75% ± 5%RH	
Time Pe	riod	Real time: 6 me Accelerated: 6			
Frequen	cy	Accelerated: 0, Real Time: 0, 3			
Batch No	0.	TF-01		TF-02	TF-03
Batch Si	ze	1000 Caps	sule	1000 Capsule	1000 Capsule
	cturing Date	01-2023		01-2023	01-2023
Date of 1	Initiation	01-2023	3	01-2023	01-2023
No. of Batches				03	
	DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUD		TUDY DATA		
1.	Reference of previous a applications with stability stud firm (if any)	approval of ly data of the			
2.	Approval of API/ DML/GMP certificate of FAPI manufacturer issued by concerned firegulatory authority of country of origin.		irm (No. Administı	also submitted copy of C 23074378) issued by For ation Gujrat State India valid till 04-07-2026.	ood & Drug Control

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.	_	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	temperature and humidity monitoring of	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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.

- 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: Cholecalciferol5600 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,

			contair	ner closure system and s	stability studies of drug
	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		
	Pharmaceutical Equivalence and Comparative Dissolution Profile		development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical		nufacturing process and ion protocols, control of product, specifications, dation of analytical is, justification of andard or materials,
			against manufa	Pharmaceutical Equivalence have been established against the Banferol soft Gelatin capsule 6500IU manufactured by Consilient Health Ireland by performing quality tests (Physical appearance, color,	
	Analytical method validation product	verification of	Firm has submitted analytical method verification study reports for drug product.		
		STABILITY S'	TUDY I	DATA	
Manufac	turer 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			
	ion of Pack er closure system)	Alu-Pvdc Bliste	er		
Stability	Storage Condition	Real time: 30°C Accelerated: 40		65% ± 5%RH C / 75% ± 5%RH	
Time Per	riod	Real time: 6 mc			
Frequenc	су	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No	Э.	TF-01		TF-02	TF-03
Batch Siz	ze	1000 Caps	ule	1000 Capsule	1000 Capsule
Manufac	turing Date	01-2023	<u> </u>	01-2023	01-2023
Date of I	nitiation	01-2023		01-2023	01-2023
No. of Batches		03			
DOCUMENTS / DATA TO BE PROVIDED A		ALONG	WITH STABILITY ST	UDY 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 FAPI manufacturer issued by concerned firegulatory authority of country of origin.		rm (No. dministr	also submitted copy of G 23074378) issued by Fo ration Gujrat State India valid till 04-07-2026.	od & Drug Control

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.	*	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	temperature and humidity monitoring of	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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.

- 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: Cholecalciferol800 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,

				ner closure system and s	stability studies of drug
				substance.	
	(Conditions & duration of Stability studies)			ty study conditions: erm: $5^{\circ}C \pm 2^{\circ}C \%$ for 36° erated: $25^{\circ}C \pm 2^{\circ}C / 60\%$	
			descrip develo proces excipio analyti proced specifi	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile		agains manuf	Pharmaceutical Equivalence have been established against the Banferol soft Gelatin capsule 800IU manufactured by Goodlife pharma Netherland by performing quality tests (Physical appearance, colour,	
	Analytical method validation product	/verification of		has submitted analyticateports for drug product.	al method verification
		STABILITY S	TUDY I	DATA	
Manufac	cturer 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			
	ion of Pack er closure system)	Alu-Pvdc Blist	Alu-Pvdc Blister		
Stability	Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Per	riod	Real time: 6 months Accelerated: 6 months			
Frequenc	су	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No	0.	TF-01		TF-02	TF-03
Batch Si	ze	1000 Caps	sule	1000 Capsule	1000 Capsule
	cturing Date	01-2023	3	01-2023	01-2023
Date of Initiation		01-2023	3	01-2023	01-2023
No. of Batches		03			
DOCUMENTS / DATA TO BE PROVIDED A		ALONG	S WITH STABILITY ST	UDY 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 Financial API manufacturer issued by concerned financial regulatory authority of country of origin.		irm (No. Administ	also submitted copy of C 23074378) issued by Fo ration Gujrat State India valid till 04-07-2026.	od & Drug Control

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.	•	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	temperature and humidity monitoring of	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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 285^{th} meeting held on 17^{th} & 18^{th} March 2022, has approved the following 02 additional sections of M/s Siam Pharmaceutical.

	chet Section (General). ished Good store (Revised)			
195.	,		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	Z	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 na	me	Omitid Sachet 20 mg/1680 mg	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each Sachet contains: Omeprazole20mg Sodium bicarbonate1680 mg	
	Pharmacotherapeutic Group of (API)		Proton pump inhibitors	
	Reference to Finished product specification	ons	Innovator's Specifications	
	EVAL	UATI	ION 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).		
Propo	sed Pack size	As po	er SRO	
Propo	sed unit price	As per SRO		
The st	tatus in reference regulatory authorities	Zegerid for Immediate Release Oral Suspension by Santarus, Inc of (USFDA Approved)		
For ge	eneric drugs (me-too status)	Risek Insta for Immediate Release Oral Suspension. by Getz Pharma.		
Name and address of API manufacturer.		Addr Telai Sodii	prazole: M/s Everest Organics limited. ress: Aroor Village, Sadasivpet Mandal, Sangareddy Dist. ngana. um bicarbonate: M/s United Chem ress: 18-Warlley Moor Lane Leeds West Workshire LS HX	
Modu	le-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.		
		Firm has submitted detailed drug substance data as per modul 3.2.S.		
	ity Studies of Drug Substance litions & duration of Stability studies)		has submitted stability study data of 3 batches of drug tance as per zone IV-A conditions.	
Modu	le-III Drug Product:	Firm	has submitted data of drug product as per module 3.2.P.	
Dissolution Profile		Firm has submitted pharmaceutical equivalence of their product against the Zegerid POWDER FOR ORAL SUSPENSION By Santarus Inc.		

		bmitted CDP results of the Zegerid POWDER FOR (s Inc.		
Analytical method validation/verification of product				
	STABII	LITY STUD	OY DATA	
API Lot No.	Omeprazole: Sodium bica			
Description of Pack (Container closure system)	Aluminium	foil sachet Pa	acked in packing box	
Stability Storage Condition			65% ± 5%RH 1 / 75% ± 5%RH	
Time Period	Real time: 6 Accelerated:			
Frequency	Accelerated: Real Time: 0			
Batch No.	T-()1	T-02	T-03
Batch Size	2000 S	achet	2000 Sachet	2000 Sachet
Manufacturing Date	06-20	023	06-2023	06-2023
Date of Initiation	06-06-	2023	06-06-2023	06-06-2023
No. of Batches	03			
DOCUMENTS / DATA T	O BE PROV	TDED ALO	NG WITH STABILITY	STUDY DATA
Reference of previous approval of a with stability study data of the firm				
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 s	ubmitted 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)			ubmitted record of data log nonitoring of real time and	

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 (C17H19N3O3S). 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
	Each capsule contains; Cefixime Trihydrate eq. to Cefixime200mg
	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
• •	SUPRAX 200 mg CAPSULE by SANOFI Ave Spain Approved
For generic drugs (me-too status)	Cefiget 200 mg Capsule by M/s GETZ Pharma
	M/s Saakh Pharma (Pvt.) Ltd. C-7/1, North Wes Industrial Zone, Port Qasim, Karachi. Pakistan.
	Firm has submitted QOS as per WHO QOS template. Firm has summarized information relator nomenclature, structure, general proper solubility, physical form, manufacturers, descrip of manufacturing process and contrapecifications, analytical procedures and validation, batch analysis and justification specification, reference standard, container closystem and stability studies of drug substance drug product.
	Firm has submitted detailed drug substance or related to nomenclature, structure, gen properties, solubility, physical form, manufactur description of manufacturing process and contrappecifications, analytical procedures and validation, batch analysis and justification specification, reference standard, container clossystem and stability studies of drug substance. Batch No. 21CF10237
(Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batcoff drug substance at both accelerated as well as time conditions. The accelerated stability data conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for months. The real time stability data is conducted $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months. Batch No. 19CF10001, 19CF10036, 19CF10084
	Firm has submitted data of drug product includits description, composition, pharmaceut development, manufacture, manufacturing product and process control, process validation protocontrol of excipients, control of drug products specifications, analytical procedures, validation

	Dissolution Profile		Batch No. 7C602, m Hodgson. Tests done: Ident Dissolution, Assay CDP: pH 1.2: More than 850 pH 4.5: More than 850 pH 6.8: More than 850	% in 15 min % in 15 min	
	Analytical method va product	alidation/verification		analytical method validation g substance as well as drug	
		STABILITY S	^		
Manu	nfacturer of API	M/s Saakh Pharma (Qasim, Karachi. Pakis		Vestern Industrial Zone, Port	
API I	Lot No.	21CF10237			
	ription of Pack tainer closure system)	5's Capsules in Alu A	lu Blisters, packed in card	board unit carton.	
Stabi	lity Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	iency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch	n No.	T-001	T-002	T-003	
Batch	n Size	2000 Capsules	2000 Capsules	2000 Capsules	
Manu	ifacturing Date	11.2021	11.2021	11.2021	
Date	of Initiation	01.12.2021	01.12.2021	01.12.2021	
No. o	of Batches		3		
	DOCUMENTS / DATA	TO BE PROVIDED	ALONG WITH STABII	LITY STUDY DATA	
1.	Reference of previous approstability study data of the f		h Submitted		
2.	Approval of API/ DML/0 manufacturer issued by authority of country of original desired and the second secon	concerned regulator	1 0	cate No. 83/2020-DRAP (K) issued by DRAP Karachi is	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Batch No.: 21CF10237 Mfg date: - Retest: - Quantity: 2kg Invoice No.: CFX/2021 Invoice date: 26.11.202	1/4210	
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 HI audit trail reports on produ	PLC software 21CFR	& Firm has submitted log	for product testing.	

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

Rema	Remarks of Evaluator:					
Sr.	Section	Observation	Reply			
No.						
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	Copy of certificate No. 89/2022-			
		report is required.	DRAP(K) dated 23.06.2022 valid till			
			28.12.2023, issued by DRAP Karachi			
			is submitted.			

- 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.

.97.	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<)-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 monohydrate5mg 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

		process control, process excipients, control of analytical procedures procedures, batch specifications, references.	development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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: Batch No. MC0087 m Pharmaceuticals AB S	Met XR 5/500 batch ST21H011Xigduo XR 5/500mg Tablet, anufactured by M/s AstraZeneca sweden. Attributes, Identification, Assay,		
	Analytical method v product	validation/verification		alytical method validation study ince as well as drug product.	
		STABILIT	Y 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.		<u>apagliflozin;</u> DG-20190327-D01-DG06-05 (2001R0056) <u>(etformin HCl;</u> 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.			
Stab	ility Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time	e Period	Real time: 6 months Accelerated: 6 months			
Freq	uency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batc	h No.	ST21H011	ST21H012	-	
Batc	h Size	5000 tablets	5000 tablets	-	
Man	ufacturing Date	08.2021	08.2021	-	
Date	of Initiation	28.08.2021	28.08.2021	-	
No.	of Batches		2		
	DOCUMENTS / DA	TA TO BE PROVIDE	ED ALONG WITH STAB	BILITY STUDY DATA	
1.	Reference of previous approval of applications with stability study data of the firm (if any)		ns Submitted		
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		ry M/s Fuxin Long Rui Ph Copy of License No.	Liao20150233 issued by FDA ill 20.12.2022 is submitted.	

		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).	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.	-		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.		
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
	 Manufacturer will place first three production batches on long term stability studies the proposed shelf life and on accelerated studies for six months as per the commitment substitute registration application. Manufacturer will perform process validation of first three batches as per the comsubmitted in the registration application. 			
198.		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<)-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 monohydrate5mg 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. Flourid 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-PI 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 dru substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance data relate 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 dru substance. Dapagliflozin; (2001R0056) Metformin HCl; MEF/10030953 (2008R0046)

	(Conditions & duration of Stability studies)		drijo substance at bot	h accelerated as well as real time
(Conditions & duration of Stability studies)			conditions. The accel at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$ time stability data is 5% RH for 24 month rest of the conditi sisbtances.) Dapagliflozin ; 16010	erated stability data is conducted \pm 5% RH for 6 months. The real conducted at 30°C \pm 2°C / 65% \pm s. (48 months for metformin HCl, ons are same for both drug
	Module-III Drug Product:		description, condevelopment, manufation process control, process control analytical procedures, batch	rence standard or materials,
Pharmaceutical Equivalence and Comp Dissolution Profile		alence and Comparati	Reference product: Batch No. LP0226 m Pharmaceuticals AB	eglu-Met XR 5/1000 batch _Xigduo XR 5/1000mg Tablet, nanufactured by M/s AstraZeneca Sweden. Attributes, Identification, Assay,
	Analytical method v product	alidation/verification		nalytical method validation study ance as well as drug product.
		STABILIT	Y 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., Sarigran Dist. Valsad, Gujrat India. 		
API L	ot No.	<u>Dapagliflozin;</u> DG-20190327-D01-DG06-05 (2001R0056) <u>Metformin HCl;</u> 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	-
Manuf	facturing Date	08.2021	08.2021	-

Date of Initiation 22.09.2021			22.09.2021	-	
No. o	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)				
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		my M/s Fuxin Long Rui P Copy of License No. Liaoning China, valid Metformin HCl; M/s Aarti Drugs Limit Copy of GMP certi 19.03.2023 issued	Pharmaceutical Co. Ltd. Liao20150233 issued by FDA till 20.12.2022 is submitted. Ted. ficate No. 20031933 valid till by Food and Drug Control t State India is Submitted.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Batch No.: DG-201903 Mfg date: 05.10.2019 EXP: 04.10.2021 Quantity: 1.5kg Invoice No.: HN19120 Invoice date: 05.12.20 Cleared by: AD I&E I Metformin HCl; Batch No.: MEF/10030 Mfg date: 03.2020 EXP: 02.2025 Quantity: 1000Kg Invoice No.: EXP/3020 Invoice date: 15.05.20	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	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		ke testing.	alytical record for product	
5.	Compliance Record of Hl audit trail reports on prod		& Firm has submitted log	Firm has submitted log for product testing.	
6.				dity monitoring of real time and	
	 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 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 App Authorization Holder	licant / Marketing	M/s Global Pharma 204-205, Industria Islamabad. (DML N	0 /	
	Name, address of Manu	facturing site.		euticals (Pvt.) Ltd. Plot No. 204- gle, Kahuta Road, Islamabad.	
	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<)-1 dated 04.01.2022 valid till 02.01.2022 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 monohydrate10mg 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, dapagliflozi (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
Tor generic drugs (me-too status)	Reg No. 112539 M/s Hilton Pharma (Pvt) Limited.
	Reg No. 112539
Name and address of API manufacturer. Module-II (Quality Overall Summary)	Reg No. 112539 M/s Hilton Pharma (Pvt) Limited. Dapagliflozin; M/s Fuxin Long Rui Pharmaceutical Co. Ltd. Flourion Industrial Park, Fumeng (Yi Ma tu), Fuxin Cit Liaoning Province China. Metformin HCl; M/s Aarti Drugs Limited, Plot No. 211-213, Road No.

		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)
(Conditions & duration of Stability studies)		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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 Produ	ct:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equiva Dissolution Profile	llence and Comparative	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 va	alidation/verification of	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
	STABILITY S	TUDY DATA
(Yi Ma tu), Fuxin City, I <u>Metformin HCl;</u>		armaceutical Co. Ltd. Flouride Industrial Park, Fumeng Liaoning Province China. ed, Plot No. 211-213, Road No. 2, G.I.D.C., Sarigram ia.
API Lot No.	Dapagliflozin; DG-2019 Metformin HCl; MEF/	90327-D01-DG06-05 (2001R0056) 10030953 (2008R0046)
Description of Pack (Container closure system) Pink to dark pink colour of 7's packed in UC of 1		r, oblong shaped film coated tablets, in Alu-Alu blister 4's.

Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$				
Real time: 6 months Accelerated: 6 months				
	Accelerated: 0, 3, 6 (Months)			
ST21C017				
5000 tablets	5000 tablets	-		
03.2021	03.2021	-		
20.04.2021	20.04.2021	-		
	2			
TA TO BE PROVIDED	ALONG WITH STAE	BILITY STUDY DATA		
approval of applications of the firm (if any)	Submitted			
y concerned regulatory rigin.	M/s Fuxin Long Rui Ph Copy of License No. Liaoning China, valid t Metformin HCl; M/s Aarti Drugs Limite Copy of GMP certif 19.03.2023 issued b Administration, Gujrat	Liao20150233 issued by FDA iill 20.12.2022 is submitted. ed. ficate No. 20031933 valid till by Food and Drug Control State India is Submitted. 827-D01-DG06-05 54-H 19 RAP Islamabad. 9953		
		alytical record for product		
IPLC software 21CFR & duct 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) Decision: Approved.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
	Real time: 6 months Accelerated: 0, 3, 6 (M Real Time: 0, 3, 6 (Mo ST21C017 5000 tablets 03.2021 20.04.2021 TA TO BE PROVIDED approval of applications of the firm (if any) GMP certificate of API y concerned regulatory rigin. The case of import). The case of import is a sheet, COA, summary are concerned regulatory rigin.	Real time: 6 months Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) ST21C017 ST21C018 5000 tablets 03.2021 20.04.00.2021 20.04.00.2021 20.04.00.2021 20.04.00.2021 20.04.00.2021 20.04.00.2021 20.04.00.2021 20.04.00.2021		

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 comsubmitted 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<)-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 monohydrate10mg 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.	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 10/1000 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				
product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.				
STABILITY STUDY DATA					

Manu	nfacturer 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 I	Lot No.		20190327-D01-DG06-05 (EF/10030953 (2008R0046		
	ription of Pack tainer closure system)	Yellow colour, oblopacked in UC of 14's		blets, in Alu-Alu blister of 7's	
Stabi	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm$			
Time	Period	Real time: 6 months Accelerated: 6 month	ns		
Frequ	nency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N			
Batch	n No.	ST21H020	ST21H021	-	
Batch	n Size	5000 tablets	5000 tablets	-	
Manu	ıfacturing Date	08.2021	08.2021	-	
Date	of Initiation	06.08.2021	06.08.2021	-	
No. o	of Batches		2		
	DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
	Reference of previous a with stability study data of	of the firm (if any)			
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).		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.	·				

	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.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Deci	sion: Approvd.			
	 Manufacturer will place first three producti proposed shelf life and on accelerated studie the registration application. Manufacturer will perform process validate 	on batches on long term stability studies throughout s for six months as per the commitment submitted in tion of first three batches as per the commitment		
	submitted in the registration application.	1		
201.	Name, address of Applicant / Marketing Authorization Holder	M/s Hansel Pharmaceuticals (Pvt) Ltd. Plot No. Pharma City, 30Km, Multan Road, Lahor 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 Caproate500mg Estradiol Valerate10mg		
	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.E. 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months. Batch No. Hydroxyprogesterone: 17-200305001, 17 200305002, 17-200305003.			
Module-III Drug Product:	Firm has submitted data of drug product including it description, composition, pharmaceutica development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications analytical procedures, 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 S	TUDY DATA			
facturer of API <u>Hydroxyprogesterone Caproate</u>				

	Xianju, Zhejiang, 31 Estradiol Valerate	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.	Hydroxyprogestero					
Description of Pack (Container closure system	m) 2ml amber colour gla	ass ampoule.				
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm$					
Time Period	Real time: 6 months Accelerated: 6 month	ns				
Frequency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N					
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						
_	ious approval of application data of the firm (if any)	ns Submitted				
2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		ry Copy of DML No. Zhe issued by FDA Zhejian 25.03.2024 Estradiol Valerate Copy of certificate/2020/193	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/Scl M/Certificate/2020/1910 dated 09.01.2020 valid til 24.01.2021, issued by Directorate of drug control Wes			
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 lattested respec	patches will be supported betive documents lib	<u> </u>				

	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.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Sr.	Section	Observation
No.		
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.

M/s News Pharma, Plot No. 42, Sunder Industrial Estate Lahore (DML No. 000775)		
M/s News Pharma, Plot No. 42, Sunder Industrial Estate Lahore. DML No. 000775		
Copy of section approval letter No. 1-14/2006-Lic dated 18.02.2013 is submitted. Liquid Injection (General)		
□ New Drug Product (NDP)☑ Generic Drug Product (GDP)		
□ Domestic sale□ Export sale☑ Domestic and Export sales		
Dy. No 24961 dated 02.09.2022		
PKR 30000/- Slip No. 10508216678 dated 29.08.2022		
Water for Injection 10ml		
Each ampoule contains; Sterile water for injection10ml		
Other antiallergics ATC Code: S01GX09		
Water for injection		
BP Specifications.		

Proposed unit price			As per SRO	
The status in reference	regulatory authorities		MHRA Approved.	
For generic drugs (me-t			Water for Injection 10 mL Reg. No. 024684 M/s Pharmatec Pakistan Karachi.	
Name and address of A	Name and address of API manufacturer.		NA	
		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 Substa	ance:		NA	
Stability Studies of Dru (Conditions & duration			NA	
Module-III Drug Produ	Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
1 **			by M/s Healthtek Kara <u>Tests done:</u> physical Alklimity, conducti	characteristics, pH, Acidity or vity, oxidizable substances, alfates, ammonium, Calcium and
Analytical method va	alidation/verification	of		analytical method verification ug substance as well as drug
	STABILIT	Y S'	TUDY DATA	
Manufacturer of API	NA			
API Lot No.	NA	_		
Description of Pack (Container closure system) 5ml Sterile solution in I			LDPE bottle, packed in a printed carton.	
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm$			
Time Period	Real time: 6 months Accelerated: 6 month	hs		
Frequency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N	•		
Batch No.	T-01		T-02	T-03

Batch	n Size		1000 ampoules	1000 -	ampoules	1000 ampoules	
Manufacturing Date 07.2021			.2021	07.2021			
Date of Initiation 19.07.2021			07.2021	21.07.2021			
	No. of Batches			20.0	3	21.07.2021	
140. 0		FNTS / DAT	A TO RE PROVIDE	'D ALONG		ILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)							
2.							
3.			curement of API wi case of import).	th NA			
4.	attested	respective ams, Raw data		testing.	s submitted ana	lytical record for product	
5.		Record of HI ports on prod	PLC software 21CFR uct testing	& Firm ha	s submitted log	for product testing.	
6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		al tempera	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.				
Rema	arks of Eval Section	uator:	Observation			Reply	
No.	Section		Observation			Кергу	
1.	1.3.5		est GMP certificate is	-	inspection report dated 28.07.2021.		
2.	3.2.P.8	point are rec	/ studies data of 2 nd and uired.	nd 3 rd time		as submitted data vide dated 13.02.2024	
•	proposed the regist Manufac submitte	turer will pla shelf life and cration applic turer will po d in the regis	d on accelerated studention. erform process validation.	lies for six	months as per	m stability studies through the commitment submitment s	tted in
203.		dress of Applation Holder	licant / Marketing		ews Pharma, F Lahore (DML	Plot No. 42, Sunder Ind No. 000775)	ustrial
	Name, add	Name, address of Manufacturing site.		Estate 1	M/s News Pharma, Plot No. 42, Sunder Industria Estate Lahore. DML No. 000775		lustrial
	Status of t	Status of the applicant		□ Impe	 ✓ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver) 		ver)
	GMP statu	us of the firm		The firm 28.07.2		l copy of inspection repor	t dated
	Evidence	of approval of	manufacturing facilit	Lic(Vo		proval letter No. 1-14 .2021 is submitted. ection	/2006-
Í	Status of application		□ New	□ New Drug Product (NDP)			

☑ Generic Drug Product (GDP)

Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale
Dy. No. and date of submission	☑ Domestic and Export salesDy. 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; Doxofylline100mg
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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

	Pharmaceutical Equivalence and Comparative Dissolution Profile		excipients, control o analytical procedure procedures, batch	ss validation protocols, control of f drug product, specifications, es, validation of analytical analysis, justification of ence standard or materials, em and stability.	
			Reference product: manufactured by M/s Tests done: ph	Reference product: Fylod Syrup, Batch No Exp. manufactured by M/s Sami Karachi. Tests done: physical characteristics, pH, identification, uniformity of dosage unit, Deliverable	
	Analytical method v product	alidation/verification		alytical method validation study ance as well as drug product.	
		STABILITY	Y STUDY DATA		
Man	ufacturer of API	M/s Bajaj Healthcare India.	e Limited Unit-1, N-128/2	216/217 MIDC, Tarapur, Boisar,	
API	Lot No.	DOX-0170222			
	cription of Pack stainer closure system)	White colour suspens	sion filled in amber colour	ed bottles.	
Stab	ility Storage Condition	Real time: 30°C ± 2°C Accelerated: 40°C ± 2			
Time	e Period	Real time: 6 months Accelerated: 6 month	ns		
Freq	uency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (M			
Batc	h No.	T-01	T-02	T-03	
Batc	h Size	45 bottles	45 bottles	45 bottles	
Man	ufacturing Date	09.2021	09.2021	09.2021	
Date	of Initiation	28.09.2021	28.09.2021	28.09.2021	
No.	of Batches		3		
	DOCUMENTS / DAT	TA TO BE PROVIDE	D ALONG WITH STAR	BILITY STUDY DATA	
1.	Reference of previous a with stability study data of		ns Submitted		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			6-KV/174 dated 03.01.2022 valid ed by FDA Maharashtra is	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Batch No: DOX-01702 Mfg: 02.2021 Exp: 01.2025 Quantity: 1kg Invoice No. ES/TP/005 Invoice date: 10.09.202 Clearance done through	58/21-21 21 h DHL.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		testing.	alytical record for product	

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

- 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
Dr. No. and data of submission	☑ 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 48 months. Batch No. 011302001, 011302002, 011302003.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical

	Pharmaceutical Equiva Dissolution Profile	alence and Comparative	process control, process excipients, control of analytical procedure procedures, batch specifications, refere container closure system. Test product: New-Zer Reference product: (manufactured by M/s Strests done: physical)	ence standard or materials, em and stability. one 2g Inj Oxidil 2g Inj, Batch No Exp. Sami Karachi. characteristics, Uniformity of ermination, pH, Assay.	
	Analytical method v	ralidation/verification of	f Firm has submitted	analytical method verification ag substance as well as drug	
	-	STABILITY	STUDY DATA		
Man	ufacturer of API		da Pharmaceutical Co. lest Medical Zone Datong	Ltd. Economic & technological Shanxi China.	
API	Lot No.	Q012105081			
	ription of Pack tainer closure system)	White to yellowish crystalline powder filled in transparent glass vial.			
Stabi	lity Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	uency	Accelerated: 0, 3, 6 (MoReal Time: 0, 3, 6 (Mo			
Batc	h No.	T-01	T-02	T-03	
Batc	h Size	1000 vials	1000 vials	1000 vials	
Man	ufacturing Date	07.2021	07.2021	07.2021	
Date	of Initiation	28.07.2021	28.07.2021	28.07.2021	
No. o	of Batches		3		
	DOCUMENTS / DA	ΓΑ ΤΟ BE PROVIDED	ALONG WITH STAB	ILITY STUDY DATA	
1.	Reference of previous a with stability study data		Submitted		
2.	Approval of API/ DML/GMP certificate of API			SX20180229 dated 06.06.2018 ssued by FDA Shanxi province	
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: 23.06.202 Clearance done by: AD	.1	
4.	Data of stability batches will be supported by attested respective documents like		Firm has submitted ana testing.	lytical record for product	

	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.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr.	Section	Observation	Reply
No.			
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	The firm has submitted following
		reference product (Oxidil 2g) is required.	details;
			Oxidil 2g Injection, Batch No. MCE
			011, Mfg date. 05.2021, Exp date
			04.2023
3.	-	Copy of AD attested invoice or clearance	The firm has submitted copy of AD
		certificate of drug substance is required.	I&E Lahore attested Invoice for
			clearance of drug substance.

- 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; Rivaroxaban20mg

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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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, D'CDP; pH 1.2: More than 850 pH 4.5: More than 850 pH 6.8: More than 850	% in 15 min % in 15 min	
	Analytical method v	validation/verification		alytical method validation study nce as well as drug product.	
	·	STABILIT	Y STUDY DATA		
Man	ufacturer of API		or Pharmaceutical Co. Loxing, Zhejiang China.	td., Yuedong Road, Paojiang	
API	Lot No.	032-200406U			
	cription of Pack ntainer closure system)	Alu-Alu Blister.			
Stab	ility Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm$			
Time	e Period	Real time: 6 months Accelerated: 6 month	ns		
Freq	uency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N	· ·		
Batc	ch No.	RIVA-20/T001	RIVA-20/T002	RIVA-20/T003	
Batc	th Size	1000 tablets	1000 tablets	1000 tablets	
Man	ufacturing Date	05.2021	12.2021	12.2021	
Date	e of Initiation	16.06.2021	24.01.2022	24.01.2022	
No.	of Batches		3		
	DOCUMENTS / DA	TA TO BE PROVIDE	ED ALONG WITH STAB	SILITY STUDY DATA	
1.	Reference of previous with stability study data		ns Submitted		
2.	Approval of API/ DML manufacturer issued by authority of country of o	y concerned regulato	ry Copy of DML vide	TONY OF LIMIT VIGE NO THE JUICELLY 19 VALID THE	
3.	3. Documents for the procurement of API with approval from DRAP (in case of import).		th Rivaroxaban Batch No.: 032-200406 Mfg date: 16.04.2020 Retest: 15.04.2025 Quantity: 0.365kg Invoice No.: XZD21-04 Invoice date: 26.03.202 Cleared by: AD I&E D	41 21	
4.			ke testing.	lytical record for product	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		& Firm has submitted log	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)		al temperature and humic		
Rem	narks of Evaluator:				

Sr. No.	Section	Observation	Observation Reply	
1.	3.2.P.8	For trial batches RIVA-20/T002 & RIVA-20/T003, stability studies data of 3 rd time point is required.		No. ted

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.

	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; Rivaroxaban15mg	
	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 Al	PI manufacturer.	M/s Zhejiang Supor Pharmaceutical Co. Ltd., Yuedong Road, Paojiang Industrial Zone, Shaoxing, Zhejiang China.	
Module-II (Quality Ove	erall Summary)	Firm has submitted QOS as per WHO QOS-PI 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: Stability Studies of Drug Substance (Conditions & duration of Stability studies)		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	
		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 60 months. Batch No. 032-141202, 032-141203, 032-141204	
Module-III Drug Produc	et:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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		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	
		Firm has submitted analytical method validation study reports for drug substance as well as drug product.	
	STABILITY S	TUDY DATA	
Manufacturer of API	M/s Zhejiang Supor I Industrial Zone, Shaoxii	Pharmaceutical Co. Ltd., Yuedong Road, Paojiang ng, Zhejiang China.	
API Lot No.	032-200406U		

	ription of Pactainer closure		Alu-Alu Blister.					
Stabi	lity Storage (Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$					
Time	Period		Real time: 6 months Accelerated: 6 months					
Frequ	uency		Accelerated: 0, 3, 6 (MoReal Time: 0, 3, 6 (Mo					
Batcl	h No.		RIVA-15/T001	RIVA	-15/T002		RIVA-15	5/T003
Batcl	h Size		1000 tablets	1000	tablets		1000 ta	blets
Manu	ufacturing Da	ite	05.2021	12	.2021		12.20)21
Date	of Initiation		16.06.2021	08.0	1.2022		08.01.2	2022
No. o	of Batches				3			
	DOCUM	ENTS / DAT	TA TO BE PROVIDED	ALONG	WITH STA	BILITY	STUDY I	DATA
1.			pproval of applications of the firm (if any)	pproval of applications Submitted 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 vide No. Zhe 20040279 valid till 30.05.21024 issued by Zhejiang FDA is submitted.				
3.				Batch N Mfg date Retest: 1 Quantity Invoice	aban o.: 032-20040 e: 16.04.2020 5.04.2025 v: 0.365kg No.: XZD21-0 date: 26.03.20 by: AD I&E I	041 21	hore	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		testing.	s submitted an	alytical r	ecord for j	product	
5.		ance Record of HPLC software 21CFR & Firm has submitted log for product testing.		g.				
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)							
	arks of Eval	uator:	01 4			D '		
Sr. No.	Section		Observation			Reply	7	
1.	3.2.P.8	For trial ba	atches RIVA-15/T002 &	z RIVA-	Submitted	vide	letter	No.

ittiiu	Activating of Livatautor.					
Sr.	Section	Observation	Reply			
No.						
1.	3.2.P.8	For trial batches RIVA-15/T002 & RIVA-	Submitted vide letter No	o.		
		15/T003, stability studies data of 3 rd time	PHL/0124/REG/057 date	ed		
		point is required.	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	M/s Pharmedic Laboratories (Pvt.) Ltd., 16-KM,
	Authorization Holder	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; Rivaroxaban10mg
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,

		and justification of s	and its validation, batch analysis pecification, reference standard, em and stability studies of drug	
Stability Studies of Dru (Conditions & duration		drug substance at both conditions. The accelerate $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$: time stability data is c 5% RH for 60 months	ability study data of 3 batches of a accelerated as well as real time erated stability data is conducted \pm 5% RH for 6 months. The real onducted at 30°C \pm 2°C / 65% \pm . 2, 032-141203, 032-141204	
Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile		description, condevelopment, manufacture process control, process excipients, control of analytical procedure procedures, batch	analysis, justification of ence standard or materials,	
		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 va	alidation/verification		nalytical method validation study nace as well as drug product.	
	STABILITY	STUDY DATA		
Manufacturer of API		r Pharmaceutical Co. I xing, Zhejiang China.	td., Yuedong Road, Paojiang	
API Lot No.	032-200406U			
Description of Pack (Container closure system)	Alu-Alu Blister.			
Stability Storage Condition	Real time: 30°C ± 2°C Accelerated: 40°C ± 2			
Time Period Real time: 6 months Accelerated: 6 months		s		
Frequency Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mon				
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.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Rem	Remarks of Evaluator:			

Sr.	Section	Observation	Reply		
No.					
1.	3.2.P.8	For trial batches RIVA-10/T002 & RIVA-	Submitted vide	letter	No.
		10/T003, stability studies data of 3 rd time	time PHL/0124/REG/057		dated
		point is required.	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; Testosterone50mg
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 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, Vadod Gujrat India
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS template. Firm has summarized information relate nomenclature, structure, general properties, solubi physical form, manufacturers, description manufacturing process and controls, specificationallytical procedures and its validation, batch anal and justification of specification, reference stand container closure system and stability studies of c substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance data relato nomenclature, structure, general propert solubility, physical form, manufacturers, description manufacturing process and controls, specification analytical procedures and its validation, batch analytical procedures and its validation, batch analytication of specification, reference stand container closure system and stability studies of disubstance. Batch No. 18006TS1RN
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batche drug substance at both accelerated as well as real t conditions. The accelerated stability data is conduct at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\%$ SW RH for 60 months. Batch No. 4016TS1RN, 4017TS1RN, 4018TS1RN
Module-III Drug Product:	Firm has submitted data of drug product including description, composition, pharmaceut development, manufacture, manufacturing process

	Pharmaceutical Equivalence and Comparative Dissolution Profile		excipients, control o analytical procedure procedures, batch specifications, refere container closure syste	analysis, justification of ence standard or materials, em and stability.		
			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 very product	alidation/verification		alytical method validation study ance as well as drug product.		
		STABILITY	STUDY DATA			
Man	ufacturer of API	M/s Ipca Laboratorie Plot No. 23-24, G.I.D.	s Limited O.C Estate, Nandesari, Vad	lodara, Gujrat India		
API	Lot No.	18006TS1RN				
	ription of Pack tainer closure system)	Alu-Alu Sachet				
Stab	lity Storage Condition	Real time: 30°C ± 2°C Accelerated: 40°C ± 2				
Time	Period	Real time: 12 months Accelerated: 6 month				
Freq	uency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (M				
Batc	h No.	C0001	C002	C003		
Batc	h Size	12000 sachet	12000 sachet	12000 sachet		
Man	ufacturing Date	01.2021	01.2021	01.2021		
Date	of Initiation	02.02.2021	02.02.2021	02.02.2021		
No.	of Batches		3			
			D ALONG WITH STAE	BILITY STUDY DATA		
1.	Reference of previous a with stability study data of		s Submitted			
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).		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.		te testing.	alytical record for product		

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

Remarks of Evaluator:

Sr.	r. Section Observation		Reply		
No.					
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.		

- 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 acid180mg		
	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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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 vaproduct	alidation/verification o		alytical method validation study nce as well as drug product.	
		STABILITY	STUDY DATA		
Man	ufacturer of API		n Village, Parawada M	Plot No. 34B, 40B & 60B, J.N. andal, Visakhapatnam District,	
API	Lot No.	18006TS1RN			
	cription of Pack ntainer closure system)	Alu-Alu Blister in uni	t carton.		
Stab	ility Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time	e Period	Real time: 12 months Accelerated: 6 months	3		
Freq	uency	Accelerated: 0, 3, 6 (Meal Time: 0, 3, 6 (Meal			
Batc	h No.	21PD-088	21PD-097	21PD-098	
Batc	h Size	2500 Tablets	2500 Tablets	2500 Tablets	
Man	ufacturing Date	04.2021	05.2021	05.2021	
Date	of Initiation	06.2021	06.2021	06.2021	
No.	of Batches		3		
	DOCUMENTS / DAT	A TO BE PROVIDE	O ALONG WITH STAB	BILITY STUDY DATA	
1.	Reference of previous a with stability study data of		s Submitted		
2.	Approval of API/ DML/manufacturer issued by authority of country of or	concerned regulatory	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.	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.			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	Firm has submitted log for product testing.	
6.			Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		

Rema	Remarks of Evaluator:					
Sr.	Section	Observation	Reply			
No.						
1.	3.2.S.7	The stability data of drug substance	Response submitted vide letter No.			
	&	submitted is only upto for 18 months and	nil dated nil. Firm has submitted			
	3.2.P.8	proposed shelf life of drug product is 24	stability data of following batches of			
		months. Justify and also submitted complete	drug substance upto 36 months (3			
		stability data of drug substance.	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	The firm has stated that it was a			
		that CDP of test and reference product show	typographic error and by mistake they			
		equivalence, whereas F2 factor for CDP at	had written F1 values in F2 column			
		pH 1.2 is 12.75 and at pH 4.5 is 11.11. The	and vice versa.			
		F2 factor is below acceptance criteria.	iteria. Correct F2 values at different pH are			
		Justify.	given below;			
			F2 at pH 1.2= 59.93			
			F2 at pH 4.5 = 52.36			
			F2 at pH 6.8 = 59.45			

- 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 Olopatadine7mg (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, Olopatadi 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. 2 nd Zhongshan Road, Chemical park, Binhai Econom Development Zone, Binhai County, Yancheng Jiang China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-F template. Firm has summarized information related nomenclature, structure, general properties, solubility physical form, manufacturers, description manufacturing process and controls, specification analytical procedures and its validation, batch analyst and justification of specification, reference standar container closure system and stability studies of drasubstance and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance data relat to nomenclature, structure, general properties solubility, physical form, manufacturers, description manufacturing process and controls, specification analytical procedures and its validation, batch analyst 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 drug substance at both accelerated as well as real tir conditions. The accelerated stability data is conduct at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The retime stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\%$ 5% RH for 36 months. Batch No. 170901, 171101, 170801, 170901, 171101
Module-III Drug Product:	Firm has submitted data of drug product including description, composition, pharmaceutic development, manufacture, manufacturing process as process control, process validation protocols, control excipients, control of drug product, specification analytical procedures, validation of analytic procedures, batch analysis, justification specifications, reference standard or material container closure system and stability.

	Pharmaceutical Equiva Dissolution Profile	alence and Comparati	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 v product	alidation/verification		analytical method verification ug substance as well as drug		
	,	STABILITY	Y STUDY DATA			
Man	ufacturer of API	M/s Binha Gaolou Cl 2 nd Zhongshan Road Binhai County, Yand	l, Chemical park, Binhai	Economic Development Zone,		
API	Lot No.	20092				
	ription of Pack tainer closure system)	5ml Sterile solution i	n LDPE bottle, packed in	a printed carton.		
Stab	llity Storage Condition	Real time: 30°C ± 2°C Accelerated: 40°C ± 2				
Time	e Period	Real time: 6 months Accelerated: 6 month	as			
Freq	uency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (M				
Batc	h No.	AU333C	AU331C	AU332C		
Batc	h Size	151 bottles (1500ml)	150 bottles (1500ml)	150 bottles (1500ml)		
Man	ufacturing Date	09.2021	09.2021	09.2021		
Date	of Initiation	08.10.2021	08.10.2021	08.10.2021		
No.	of Batches		3			
	DOCUMENTS / DAT	ΓA TO BE PROVIDE	D ALONG WITH STAF	BILITY STUDY DATA		
1.	Reference of previous a with stability study data of		ns Submitted			
2.	Approval of API/ DML/ manufacturer issued by authority of country of or	concerned regulator	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).		Batch No.: Mfg date: 05.2021 Quantity: 0.25kg Invoice No.: 20144AL Invoice date: 20.10.202	Batch No.: Mfg date: 05.2021		
4.			testing.			
5.	Compliance Record of HPLC software 21CFR & Firm has submitted log for product testing. audit trail reports on product testing			for product testing.		

6.	Record of Digital data logger for temperature and	Firm has submitted record of digital data logger for
	humidity monitoring of stability chambers (real	temperature and humidity monitoring of real time and
	time and accelerated)	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: Pregabalin330mg	
	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 ma	nufacturer.	M/s CTX Lifesciences Pvt. Ltd., Block No.	
		251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230, Gujarat, India	
Module-II (Quality Overall S	ummary)	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 Sub (Conditions & duration of Sta		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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 Dissolution Profile	e and Comparative	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 (<i>name not mentioned</i>) 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 produc		Firm have submitted method validation studies including linearity, range, accuracy, precision, specificity and robustness.	
ST	TABILITY STUDY DA	ATA	
Manufacturer of API		ces Pvt. Ltd., Block No. 251-252 Sachin, Sachin, Surat – 394 230, Gujarat, INDIA	
API Lot No. 21PL000050			
Description of Pack	Alu-Alu blister packed in unit carton		

(Container c	losure system)				
Stability Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Period		Real time: 6 months Accelerated: 6 months			
Frequency		Accelerated: 0, Real Time: 0, 3			
Batch No.		TPU001		TPU002	TPU003
Batch Size		2500 tablets		2500 tablets	2500 tablets
Manufacturi	ng Date	12-2021		12-2021	12-2021
Date of Initia	ation	21-12-2021		23-12-2021	25-12-2021
No. of Batch	nes			03	
		Administrativ	ve Por	tion	
	Reference of previous approver tability study data of the firm		s with	N/A	
n				PI 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.	
	Documents for the procurement of A approval from DRAP (in case of import).		with	Firm has submitted of EI/3012100599 dated 1 of 50kg of Pregabalin (E name of M/s Wimits I Ltd., attested by AD dated 29-11-2021	9-11-2021 for import Batch# 21PL000050) in Pharmaceuticals (Pvt.)
a	Data of stability batches v ttested respective document Raw data sheets, COA, summ	t like chromatog	grams,	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
	Compliance Record of HPLoudit trail reports on product t		FR &	+	
6. Record of Digital data logger for tempe humidity monitoring of stability chambers and accelerated)					ture and humidity
Remarks of	Evaluator XI:				
Section	Observations			Firm's response	
Submit differential fee Rs. applied product is a new d New formulation			• Firm has submitted differential Fee Rs. 4 on deposit slip No. 5205891368 as product is a new drug molecule. However online verification the invoice amount 30,000/- while paid amount is Rs. 45,000/-		5891368 as applied cule. However, upon voice amount is Rs.
1.3.4	• Submit copy of Manufacturing License (I	oy of valid Drug •		m has submitted a copy of	
1.4 • Clarification is required applied for generic drug p		l as you have	The firm submitted that it was mistakenly dorn please considered as New Drug Molecule and submitted revised document		Drug Molecule and

	the applied product is a new drug	
1.5.2	molecule / New formulation • 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
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, 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.

	anufacturer will perform process validation of first three batches as per the commitment submitted 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 Fumarate10mg		
	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 Substar (Conditions & duration of Stability)		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months.
Module-III (Drug Product):	Module-III (Drug Product):	
Pharmaceutical Equivalence Dissolution Profile	and Comparative	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.
STA	ABILITY STUDY DA	ATA
Manufacturer of API	Zhongshan Torch Guangdong Province	orporation Limited., No.6 Zhongjing RD, Hi-Tech Industrial Development Zone, , China
API Lot No.	TAK09-220101	
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton.	
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{RH}$	

		Accelerated: 40	$^{\circ}$ C ± 2	2°C / 75% ± 5%RH	
		Real time: 3 months Accelerated: 3 months			
Frequen	ncy	Accelerated: 0, Real Time: 0, 3		*	
Batch N	No.	TVF001		TVF002	TVF003
Batch S	ize	2500 Table	2500 Tablets 2500 Tablets		2500 Tablets
Manufa	cturing Date	06-2022 06-2022		06-2022	06-2022
Date of	Initiation	18-06-2022	2	20-06-2022 22-06-	
No. of I	Batches			03	
		Administrative	Porti	ion	
1.	Reference of previous approval stability study data of the firm (if		with	N/A	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			A *	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		oroval	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 dat supported by attested like chromatograms, Ra summary data sheets etc	respective document aw data sheets, COA,
5.	Compliance Record of HPLC soft trail reports on product testing	ftware 21CFR &	audit	Not submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)				toring of stability
	ks of Evaluator ^{XI} :				
Section				Firm's response	
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)		Firm has submitted a copy of valid DML		or valid DML
1.6.5	Valid cGMP certificate / DN Substance manufacturer issu	 Valid cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required To ZI is 		e firm has again submitificate of M/s Enantatited., No.6 Zhongjing the Hi-Tech Industrial ongshan City, Guangdoued by Guangdong Phansociation China valid upt	tiotech Corporation Road, Zhongshan Development Zone, ng Province, China rmaceutical Industry

	1		T I
3.2.S.4	 Justification shall 	be submitted for using	• Firm has revised chromatographic method as per
	different chroma	tographic conditions	drug substance manufacturer
	(wavelength, injection volume, mobile		• Fumaric acid content is performed and revised
	phase) for assay test by drug product		COA of drug product manufacturer is submitted
	manufacturer than that by substance		Corr of drug product mandracturer is submitted
	manufacturer	i that by substance	
		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
		be submitted for not	
		for fumaric acid content	
		drug substance by drug	
	product manufactur	rer as recommended by	
	drug substance man	ufacturer	
3.2.P.2	• Compatibility stu	idies of the Drug	• Firm has submitted compatibility studies of the
	Substance(s) with	excipients shall be	drug substance with excipients.
		alitative composition of	• The firm has submitted details of reference
		ot similar to innovator /	product
	reference product.		Name: Voniza 10mg tablets
	Applied product	TAKECAB Tablets	Manufacturer: M/s Hilton Pharma
	Applied product		
	17	10mg	B No#: 141102
	Vonoprazan	Vonoprazan	Mfg date: 11-2021
	Fumarate	Fumarate	Exp date ; 11-2023
	Lactose	D-mannitol,	• However, the brand name mentioned in
	monohydrate,	microcrystalline	pharmaceutical equivalence studies was vonnp
	Mannitol, Avicel	cellulose,	10mg tablet
	Ph 101, Klucel,	croscarmellose	• Firm has submitted revised pharmaceutical
	Cross carmellose	sodium,	equivalence report in which test for uniformity
	sodium, sodium	hydroxypropyl	of dosage units has been performed.
	starch glycolate,	cellulose, fumaric	• The firm submitted that the innovator product is
	magnesium	acid, magnesium	_
	stearate, Tabcoat	stearate,	Takeda that is not easily available that is why we
			use the local product which is easily available in
	white, isopropyl	hypromellose,	the market
	alcohol, purified	macrogol 6000,	
	water	titanium oxide,	
		yellow ferric oxide	
		nce product including	
	manufacturer, batch	number, manufacturing	
	and expiry date u	ised in pharmaceutical	
	equivalence studies	_	
	_	rator product including	
		facturer, batch number,	
	1	expiry date used in CDP	
	studies shall be sub		
		be submitted for not	
		ests in pharmaceutical	
		es including the tests	
	-	novator product review	
	document (uniform	ity of dosage units)	
	• Justification shall	be submitted for not	
		ceutical equivalence and	
		t the innovator product	
3.2.P.5		ation of dissolution	• The firm submitted that we have considered
3.2.1.3	•	olution medium and time	
	_		PMDA Japan approved product as innovator
		nded by USFDA for the	wherein details of dissolution specifications
		s. (use of phosphate	have not been revealed hence we follow the
	_	tead of 0.05M acetate	general pharmacopeial guideline for dissolution
	_	Q at 30 minutes instead	specifications and parameters for immediate
	on Q at 15 minutes)	<u> </u>	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.

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 Fumarate20mg

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)	of drug substance at both accelerated as well as real
Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control 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 me validation/verification of pro		Firm has submitted studies including lir precision (Repeatabil robustness and system	nearity and range, a ity, Intermediate), sp	accuracy,
	STABILITY	STU	DY DATA		
Manufacturer of API		RD,	Enantiotech Corporati Zhongshan Torch Hi- e, Guangdong Province	Tech Industrial Dev	
API Lot No.		TAK	X09-220101		
Description of Pack (Container closure syst	tem)	Alu-	Alu Blister packed in u	nit carton.	
Stability Storage Cond	lition		time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\%$ elerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 7$		
Time Period			time: 3 months elerated: 3 months		
Frequency			elerated: 0, 3 (Months) Time: 0, 3 (Months)		
Batch No.			TVM001	TVM002	TVM0 03
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	
	Adminis	trativ	ve Portion		
1.	Reference of previous app. of applications with stal study data of the firm (if any	bility			
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		urer M/s Enantiotech Corporation Limited., Zhongshatory Torch Hi-Tech Industrial Development Zon		hongshan nt Zone, hongshan
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Firm has submitted copy of Form 6 dated 27-05-202 for import of 500g Vonoprazan fumarate in name M/s Wimits Pharmaceuticals Pvt. Ltd., Laho attested by AD (I&E) DRAP Lahore dated 27-0 2022.		n name of Lahore
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.		supported by atteste chromatograms, Raw	ed respective docum	nent like

5.	software	nce Record of HPLC 21CFR & audit trail a product testing	
6.	Record o temperate monitoria	f Digital data logger for are and humidity	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 val License (DML)	id Drug Manufacturing	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	different chroma (wavelength, inject phase) for assay manufacturer that manufacturer • Justification shall performing the t content in batch and by drug produ	be submitted for using stographic conditions etion volume, mobile test by drug product in that by substance be submitted for not sest for fumaric acid alysis of drug substance ct manufacturer as y drug substance	 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	Substance(s) with provided as the qua	excipients shall be alitative composition of not similar to innovator TAKECAB Tablets 20mg	 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
	Vonoprazan Fumarate Lactose monohydrate, Mannitol, Avicel Ph 101, Klucel, Cross carmellose sodium, sodium starch glycolate, magnesium stearate, Tabcoat white, isopropyl alcohol, purified water	Vonoprazan Fumarate D-mannitol, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, fumaric acid, magnesium stearate, hypromellose, macrogol 6000, titanium oxide, yellow ferric oxide	 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

3.2.P.5	 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 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
3.2.P.8	Submit stability study data of applied	 single unit tablet of vonprazan Stability study data of applied product at 6th
	 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 	 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)	
	CO CO CO CO TO		
	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: Levosulpiride25mg	
	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 analy and justification of specification, reference standa container closure system and stability studies of dr substance and drug product. Module III (Drug Substance) Firm has submitted detailed drug substance data related to nomenclature, structure, general properties of manufacturing process and controls, specification analytical procedures and its validation, batch analy and justification of specification, reference standa container closure system and stability studies of dr substance. Stability Studies of Drug Substance (Conditions & duration of Stability studies) Firm has submitted stability study data of 3 batches drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 30°C ± 2°C / 65% SW RH for 48 months. (Batches: LC/LSP/180304, LC/LSP/180304)
to nomenclature, structure, general properti solubilities, physical form, manufacturers, description of manufacturing process and controls, specification analytical procedures and its validation, batch analytical procedures and stability studies of drugstandary analytic
Substance (Conditions & duration of Stability studies) drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The retime stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\%$ 5% RH for 48 months. (Batches: LC/LSP/180304, LC/LSP/180304)
LC/LSP/180306)
Module-III (Drug Product): Firm has submitted data of drug product including description, composition, pharmaceutical developme manufacture, manufacturing process and procedures, validation protocols, control excipients, control of drug product, specification analytical procedures, validation of analytical procedures, batch analysis, justification specifications, reference standard or material container closure system and stability study.
Pharmaceutical Equivalence and Comparative Dissolution Profile Firm has submitted pharmaceutical equivalence of the product against the product Levopraid 25mg tablet M/s Pacific Pharma Pvt. Ltd., by performing qual tests (Description, dissolution, disintegration times 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 Buf (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 analytic solution, linearity, range, limit of detection, limit quantitation.
STABILITY STUDY DATA
Manufacturer of API M/s Varahi International., Nr. Old Ruby Coach & R Crossing, Opp Naroda Rly. Station Ahmedabad Gujrat, Inc.
API Lot No. 31L01Z2122-019
Description of Pack (Contain and Journal and Lorentz Alu-Alu blister packed in card board 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

			Accel	erated: 6 months			
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)					
Batch No.	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			
		Adm	inistra	tive Portion			
1		Reference of pre approval of applications stability study data of the (if any)		N/A			
		API by hority	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	3. Documents for the procurement of API with approval from DRAP (in case of import).		with				
4. Data of stability batches		tested like data	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 software 21CFR & audreports on product testing		t trail					
6. Record of for temper monitorin chambers accelerate		1 1		and accelerated) is submitted			
	of Evaluato						
1.3.5	report o	GMP certificate / GMP in finantificate in an interest of manufacturing unit coast three years	_				
1.6.5	Valid copy of cGMP certificate / DML the Drug Substance manufacturer issued relevant regulatory authority of country origin is required			certificate of M/s Varahi International., Opp;			

3.2.S.4	• Copies of the Drug substance	Copies of the Drug substance specifications and
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% 	 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.
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	• Firm has submitted copy of invoice for import of
	API with approval from DRAP (in case of	25kg Levosulpride IH in name of M/s Aptcure
	import).	Private Limited attested by AD (I&E) DRAP
	Detailed raw data sheet is not submitted	Lahore dated 02-12-2021.
	• The submitted COA of stability study does	Detailed raw data sheet containing calculation
	not show the time point and storage	details are not submitted
	conditions of stability study	• 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.

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):	its desc developr process protocols product, validatio analysis, standard	submitted data of drug cription, composition, ment, manufacture, and process control, p s, control of excipients specifications, analy on of analytical pr justification of specific or materials, contained	pharmaceutical manufacturing process validation s, control of drug tical procedures, pocedures, batch cations, reference
	Pharmaceutical Equivalence and Comparative Dissolution Profile		d Firm has submitted pharmaceutical equivalen of their product against the product Vimos 500mg/20mgTablet by M/s Astrazeneca Sweder CDP has been performed against the sar product Vimovo 500mg/20mg Tablet by M/s Astrazeneca Sweden in Acid media (0.1N HC) acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated phosphate buffer are in acceptable range. The values of f2 factor are not calculated for esome prazole as it is unstable in acidic media at acetate buffer. The values of f2 factor are not calculated for naproxen as it is enteric coated and not table ruptured in acidic media and acetate buffer.		product Vimovo razeneca Sweden. gainst the same gainst (0.1N HCl), phate Buffer (pH or calculated in ole range. The same gainst the same gains
	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 Laboratorio DE MEXICO S.A DE 0 62578 Jiutepec Morelos Esomeprazole: M/s Metrochem API F Road Phase – I, IDA, J (Dist), Telangana (State	C.V km 4. s Mexico Private Lineedimetla	.5 Carretera Federal Cumited., Unit-I Plot No	ernavaca-Cuautla . 62/C/6 Pipeline
API Lot No.		Naproxen: ANMA0003 Esomeprazole: ESM/18			
Description of Pack (Container closure sys	tem)	Alu Alu blister packed in unit carton			
Stability Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
		Real time: 6 months Accelerated: 6 months			
		Accelerated: 0, 3, 6 (MorReal Time: 0, 3, 6 (Mor			
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 Ba	atches			03
	Administrative Portion			
1.		Reference of previous a applications with stability of the firm (if any)		
2.		Approval of API/ I certificate of API maissued by concerned authority of country of or	anufacturer regulatory	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). Esomept Firm has 35kg Esc of M/s H (I&E) DI Naproxe Firm has 175kg M Pharmace		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		
Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.		supported by attested respective document like chromatograms, Raw data sheets, COA, summary		
5.				Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.		temperature and monitoring of stability (real time and accelerated	humidity chambers	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted
	of Evaluator		T	
Sectio n	Observation	ns	Firm's re	esponse
1.4	product whil generic drug	applied for a new drug le the applied product is a product, clarify		
1.6.5	both the manufactur Naproxen regulatory origin is reconstructed. Address of M/s Dr.	er of Esomeprazole and issued by relevant authority of country of quired of manufacturing site of	The firm has submitted copy of cGMP certificate of M/Metrochem API Pvt. Ltd., Unit-I Plot No. 62/C/6 Pipeling 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	

		 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 Químicas 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 Químicas 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.

	 M/s Horizon Healthcare (Pvt) Ltd., Plot No.35-A, Small Industrial Estate, Taxila,
	M/s Horizon Healthcare (Pvt) Ltd., Plot No.35-A, Small Industrial Estate, Taxila,

<u></u>	Г	
	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: Retapamulin10mg (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,

			process and control procedures and its and justification of	scription of manufacturing is, specifications, analytical verification, batch analysis of specification, reference closure system and stability stance.
	(Conditions & duration of Stability studies) Module-III (Drug Product): Find the stability of the stabilit		batches of drug subs well as real time of stability data is cond ± 5% RH for 6 more	d stability study data of 3 stance at both accelerated as conditions. The accelerated ducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$ inths. The real time stability at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$
			including its of pharmaceutical de manufacturing pro process validation excipients, contr specifications, validation of ana analysis, justifica	cess and process control, in protocols, control of ol of drug product, analytical procedures, lytical procedures, batch ation of specifications, I or materials, container
	Comparative Dissolution Profile		equivalence of their	bmitted pharmaceutical product against the product nent 1% w/w by M/s
	Analytics validatio	al method n/verification of product	Firm has subm validation studies linearity and ran detection limit, robustness.	s including specificity, age, accuracy, precision,
	L	STABILITY STUDY D	ATA	
Manufacturer of API		M/s Sumar Biotech LLP., Plot No# 112, 113, 114 GIDC Estate Gozariva Tal. & Dist: Mehsana-382825, Gujarat, India.		GIDC Estate Gozariva Tal.
API Lot No.		SBL/SRD/RTP/19/08/061		
Description of Pack (Container closure syst	em)	Aluminium tube which sealed with aluminium seal and capped with screen plastic cap packed in standard unit carton		eal and capped with screw
Stability Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Period		Real time: 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 applications with stability study data the firm (if any)			
2.	certificate of API manufacturer issu	The firm has submitted copy of cGMP certificate of M/s Sumar Biotech LLP., Plot of 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.	_	API 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		
supported by attested respective		be Firm has submitted data of stability batches ive supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.		
5.		are Compliance Record of HPLC software 21CFR uct & audit trail reports on product testing is submitted		
6.	temperature and humidity monitor	for Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted		
Remarks o	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 	new drug product because no local brand available in Pakistan.		
1.6.5	 Valid GMP certificate / DML of Drug Substance manufacturer issued by relevan regulatory authority of country of origin is required 	certificate of M/s Sumar Biotech LLP., Plot		
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	batches as per minutes of 293 rd meeting of registration board, implementation of common		
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 Analytica Method Verification studies of retapamulin drug substance. Analytical Method Verification studies including specificity accuracy and repeatability (method precision) 	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 $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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.

in the registration a	ppncation.	
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: Famotidine40mg
	Pharmaceutical form of applied drug	Dry powder for suspension
	Pharmacotherapeutic Group of (API)	Anti-Ulcerative

Reference to Finished product	USP
specifications	
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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		verificati	nas submitted analyt ion studies including , precision.	
	STAB	ILITY STUDY	DATA		
			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 sys	tem)	Amber glass b	ottle		
Stability Storage Cond	lition	Real time: 30° Accelerated: 4		65% ± 5%RH C / 75% ± 5%RH	
Time Period		Real time: 3 n Accelerated: 3			
Frequency		Accelerated: 0 Real Time: 0,			
Batch No.		T1		T2	Т3
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			
	Ac	dministrative l	Portion		
1.	Reference of previous applications with stab of the firm (if any)		N/A		
2.			of M/s S Plot No. Sangared issued by Telangar	has submitted copy of co MS Lifesciences India Li 180/2, Kazipalli (V), I Idy District, Telangana- y Drugs Control Administra a India valid upto three si usue (Date of issue 09-08-2	mited., Unit-I, Jinnaram (M), 502319, India ration Govt. of years from the
3.	Documents for the procurement of API with approval from DRAP (in case of import).		invoice finame of	s submitted copy of form for import of 200kg Famo f M/s Siza International by AD (I&E) DRAP Lahor	otidine USP in l (Pvt.) Ltd.,
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.		supporte chromato	d by attested respective ograms, Raw data sheets, C	document like
5.				nce Record of HPLC softv l reports on product testin	

6.	temperature and humidity humidity monitoring of stability chambers (real time and accelerated) humidity monitoring of stability chambers (real time and accelerated)					
Remarks o	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 GMP certificate, clarify	1.6.5 is different than that given in submitted				
3.2.S.4	Copies of the Drug substance specifications and ana	• •				
	the Drug substance by Drug product manufacturer is					
	Analytical Method Verification studies including sp					
2.2 P. 1	precision) performed by the Drug Product manufact	· ·				
3.2.P.1	Provide information including type of diluent, its co and regulatory status in Pakistan for the diluent wh	1				
3.2.P.2	drug.	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				
3.2.P.2	 Submit results of drug excipient compatibility students product is not similar to reference product 	ay as the qualitative composition of applied				
	• Justification is required as tests for antimicrol	nial preservative content and efficacy of				
	preservative are not performed	siai preservative content and efficacy of				
	Pharmaceutical equivalence studies against the inno	ovator/reference product shall be submitted				
3.2.P.5	• Clarify the batch size mentioned in batch analysis of					
	bottles, For 120ml;392 bottles)					
3.2.P.6	• COA of primary / secondary reference standard provided.	including source and lot number shall be				
3.2.P.8	• You have mentioned batch size of applied product i bottles, For 120ml;392 bottles", clarify					
	• Submit stability study data of applied product at 6 th	_				
	• In use stability study of reconstitution suspension s	hall be submitted				
Decision: 1	Registration Board deferred the case for submission	of reply to the above cited shortcomings.				
218.	Name, address of Applicant / Marketing	M/s Jawa Pharmaceuticals Private Limited.,				
	Authorization Holder	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					
		☐ Importer				
		\square Is involved in none of the above (contract				
		giver)				
	GMP status of the Finished product	Not submitted				
	manufacturer	T vot sustantes				
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of				
	2. defice of approval of manufacturing facility	additional section dated 25-06-2019				
		specifying Sachet General Section.				
	Status of application	□ New Drug Product (NDP)				
	2 approximation	☐ New Drug Froduct (NDF) ☐ Generic Drug Product (GDP)				
		M Ochche Ding Frounct (ODF)				

Intended use of pharmaceutical product	☑ Domestic sale
	☐ Export sale
Dy No and data of submission	☐ 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: Racecadotril10mg
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.

	Pharmaceutical Equivalence and Comparative Dissolution Profile Analytical method validation/verification of		pharmaceutical developmanufacturing process process validation preexcipients, control specifications, analytical validation of analytical analysis, justification reference standard or closure system and stable Not submitted	otion, composition, oment, manufacture, and process control, otocols, control of of drug product, rtical procedures, l procedures, batch of specifications, materials, container ility study.
	product		Precision, Specificity, li robustness.	
	S	FABILITY STUDY D	ATA	
Manufacturer of	[°] API		ited., India, 8-2-293/174/ Banjara Hills, Hyderabad	
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	e Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%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 I	Date	10-2021	10-2021	10-2021
Date of Initiatio	n	27-10-2021	28-10-2021	29-10-2021
No. of Batches			03	
		Administrative Porti	on	
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 cop in the name of M/s Sy Plot No. 25/B, Phase-I (V), Quthbullapur (M), I District, Telangana Sta Drugs Control Admin State India valid upto 0	med Labs Limited., III, IDA, Jeedimetla Medchal - Malkajgiri te, India., issued by histration Telangana
3.	Documents for the procurement of API with approval from DRAP (in case of import).		The firm submitt 633/2020/DRAP-AD-Cl 2020 for "permission to guidelines for import of	D(I&E) dated 13-01- o Import API as per

			material for the purpose of test/analysis and stability studies" containing Racecadotril 15gm issued by AD (I&E) DRAP Lahore	
attested respective document like supported l		supported by attested respective documents like Raw data sheets and summary data		
5.	Compliance Record of HPLC sof & audit trail reports on product tes		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)			
Remarks of H	Evaluator ^{XI} :			
	Observations			
1.3.4	• Submit copy of valid Drug Manufac	cturing License	e (DML)	
1.3.5			of the applicant conducted with in last three	
1.5.5	• Indicate Pharmacological class of the	ne API (drug si	ubstance) with proper reference	
1.5.6	• Clarification is required for term formulation	"Product is J	PL" in Pharmacopoeial Status of applied	
1.6.5	regulatory authority of country of or	rigin is require	ubstance manufacturer issued by relevant d ction 1.6.5 is different than that given in	
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 			
3.2.P.2	Analysis (CoA) of the same batch for Pharmacoutical against language studies			
3.2.P.5	• The applied product is racecadotril ranelate is mentioned in specification	 Pharmaceutical equivalence studies against the innovator/reference product shall be submitted 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 		
3.2.P.6	•	ence standard	including source and lot number shall be	
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: Res	gistration Board deferred the case f	or submission	of reply to the above cited shortcomings	
Name, address of Applicar Marketing Authorization Holder		M/s Davis Pharmaceutical Laboratories., Plot No. 121 Industrial Triangle, kahuta Road, Islamabad		
	Name, address of Manufacturing site.		Pharmaceutical Laboratories., Plot No. 121, angle, kahuta Road, Islamabad	
	Status of the applicant	☑ Manufactu☐ Importer☐ Is involved	rer I in none of the above (contract giver)	
	GMP status of the Finished product manufacturer		mitted copy of cGMP certificate dated 15-02- n 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: Dexlansoprazole30mg
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

	ı				
	Stability studies) Module-III (Drug Product):		$40^{\circ}C \pm 2^{\circ}C$ / 75% \pm 5% RH for 6 months. The real time stability data is conducted at 30°C \pm 2°C / 65% \pm 5% RH for 36 months.		
			Firm has submitted data of dru description, composition, pharm manufacture, manufacturing proc process validation protocols, cont of drug product, specifications, validation of analytical proce justification of specifications, materials, container closure system	naceutical development, ess and process control, rol of excipients, control , analytical procedures, dures, batch analysis, reference standard or	
	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 validation/verification product		Firm has submitted analytical m including Accuracy, Repeatability robustness, linearity.		
	1	STABILI	ΓΥ STUDY DATA		
M/s Vis			pellets: on Pharmaceuticals Pvt. Ltd., Plot No. 22-23, Industrial Kahuta Road, Islamabad Pakistan.		
API Lot No.		DLP664	,		
Description of Pack		ister packed in unit carton			
Stability Storage C	Condition		30°C ± 2°C / 65% ± 5%RH d: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: Accelerate	6 months d: 6 months		
Frequency			d: 0, 3, 6 (Months) : 0, 3, 6 (Months)		
Batch No.		T-015	T-016	T-017	
Batch Size		5000 capsule	5000 capsule	5000 capsule	
Manufacturing Da	te	01-2021	01-2021	01-2021	
Date of Initiation		01-2021	01-2021	01-2021	
No. of Batches			03		
			strative Portion		
1.	Reference of previo of applications wi study data of the firm	th stability	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 Vision Pharmaceuticals issued o inspection conducted on 11-02-20 The firm have submitted copy of Pharmaceuticals (Pvt) Ltd., renework.	n 31-07-2019 based on 19. of DML of M/s Vision	

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

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

studies are not submitted

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: Dexlansoprazole60mg
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

	Module-III (Drug Product): Pharmaceutical Equivalence and Comparative Dissolution Profile		stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$ $\pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.	
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control 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.	
			Firm has submitted equivalence of their product Wilsop 60mg cape Pharmaceuticals. CDP has been perform product Wilsop 60mg cape Pharmaceuticals in Acid acetate buffer (pH 4.5) (pH 6.8). The values of acceptable range.	product against the psule by M/s Wilson's ned against the same psule by M/s Wilson's d media (0.1N HCl), & Phosphate Buffer
	Analytical method validation/verification of product		Firm has submitted analytical method validation studies including Accuracy, Repeatability, intermediate Precision, robustness, linearity.	
		STABILITY STUDY	DATA	
Manufactu	rer of API	Source of pellets: M/s Vision Pharmaceuticals Pvt. Ltd., Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan.		
API Lot N	0.	DLP664		
Description (Container	n of Pack closure system)	Alu-alu blister packed in unit carton		
Stability S	torage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Perio	od	Real time: 6 months Accelerated: 6 months		
Frequency	_	Accelerated: 0, 3, 6 (Meal Time: 0, 3, 6 (Meal		
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 Ini	tiation	01-2021	01-2021	01-2021
No. of Bat	ches		03	
-		Administrative Por	T	
1.	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.		
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)		
Remarks	of Evaluator ^{XI} :		
Section	Observations		
1.3.4	Submit copy of valid Drug Manufacturing Licer	nse (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 authority of country of origin is required	manufacturer issued by relevant regulatory	
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	 studies are not submitted 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

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 26 th 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 Montelukast4mg		
	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		
	Proposed unit price The status in reference regulatory authorities	As per SRO SINGULAIR 4mg oral granules USFDA Approved		
	1			
	The status in reference regulatory authorities	SINGULAIR 4mg oral granules USFDA Approved Montika 4mg Sachet by M/s Sami Pharmaceuticals		

			substance and drug product is submitted.	
Module III (Drug	Stability studies Module-III (Drug Product):		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 Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 36 months.	
Stability studies				
Module-III (Drug			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 product		Firm has submitted method verification studies including specificity, accuracy and precision.		
	STABILITY S	TUDY DATA		
Manufacturer of API		harmaceutical Co., Ltd., Jiangkou Development Zone, , Zhejiang Province, China.		
API Lot No.	11031-220404			
Description of Pack (Container closure system)	_	nular powder filled in Megi paper foil further packed in		
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	The state of the s	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 applications with firm (if any)	previous approval of stability study data of the	Not submitted		
	DML/GMP certificate of	The firm has submitted copy	y of cGMP certificate of M/s	

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	regulatory authority of country of origin. I	Zhejiang Tianyu Pharmaceutical Co., Ltd., No.15, Donghai 5 th 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.	attested respective documents like a	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw lata 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	
Remar	ks of Evaluator ^{XI} :		
Section	on Observations	Firm's response	
1.6.5	Valid copy of cGMP certificate / DML Drug Substance manufacturer issued relevant regulatory authority of country origin shall be submitted	by 20050431 of M/s Zhejiang Tianyu	
3.2.S.	manufacturer has submitted specification Vortioxetine HBr instead of Monteluk Sodium • The time point and ratio of mobile pha selected for gradient program in assay test drug substance is different than U monograph, clarify • Results of specificity test in analytic method verification studies is not submitte • Submit Certificate of Analysis of the sat batch of drug substance used during produ development and stability studies from Dr Substance manufacturer.	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 cal ed. me	
3.2.P.	the innovator/reference product shall submitted • Details of innovator/comparator product including batch number, manufacturing date expiry date against which CDP studies performed shall be submitted	be 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.	Justification shall be submitted for a including the test for uniformity of dosa units in finished product specifications as a USP monograph	sage dosage units test	
3.2.P.	• •	tes reference standard and it follows USP ille specifications	

	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 29 th 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
De Ne and date of enhanced as	☑ 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: Pregabalin150mg
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.
Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control 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				
	Analytical method va	alidation/verification of			
		STABILITY S	STUDY DATA		
Manu	nfacturer of API	•	/s Progress Life Sciences Pvt. Ltd., Unit-III, Plot No. 23&24, Jawaharlal Nehru narma City, Thanam (V), Parawada (M), J-311, Bhosari MIDC, Pune - 400 026 aharashtra, India		
API I	Lot No.	PPR/21006			
	ription of Pack tainer closure system)	Alu-Alu blister packed in unit carton			
Stabil	lity Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch	ı No.	T001	T002	T003	
Batch	Size	1500 Cap	1500 Cap	1500 Cap	
Manu	facturing Date	02-2023	02-2023	02-2023	
Date	of Initiation	15-02-2023	16-02-2023	17-02-2023	
No. o	f Batches		03		
		Administr	rative Portion		
1.	Reference of previous with stability study da	approval of applications ta of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of		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).		_		
4.	attested respective documents like		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 The firm has submitted record of Digital data logger for and humidity monitoring of stability chambers temperature and humidity monitoring of stability (real time and accelerated) chambers (real time and accelerated)

	Ren	narks	of	Eval	luator XI:	
ı						7

	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 29 th 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
De Ne and date of enhanced as	☑ 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: Pregabalin300mg
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.
Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch

			T	1
				of specifications, reference ontainer closure system and
dissolution profile				
	Analytical method va	alidation/verification of	Firm has submitted analytic including specificity, Accu	cal method verification studies tracy, Precision
		STABILITY S	STUDY DATA	
Manu	facturer 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 L	Lot No.	PPR/21006		
	ription of Pack rainer closure system)	Alu-Alu blister packed	in unit carton	
Stabil	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequ	ency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch	No.	T004	T005	T006
Batch	Size	1500 Cap	1500 Cap	1500 Cap
Manu	facturing Date	02-2023	02-2023	02-2023
Date	of Initiation	15-02-2023	16-02-2023	17-02-2023
No. o	f Batches		03	
		Administr	rative Portion	
1.	Reference of previous with stability study da	approval of applications ta of the firm (if any)	N/A	
2.			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		
· · · · · · · · · · · · · · · · · · ·		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		

Record of Digital data logger for temperature The firm has submitted record of Digital data logger for and humidity monitoring of stability chambers temperature and humidity monitoring of stability (real time and accelerated) chambers (real time and accelerated) Remarks of Evaluator XI: Section **Observations** Response 1.3.5 • Submit copy of cGMP certificate / • Firm has submitted copy of cGMP certificate **GMP** inspection report of dated 22-08-2022 issued based on inspection manufacturing unit conducted with in conducted on 16-08-2022 last three years 1.6.5 • Valid copy of cGMP certificate / DML • Firm has submitted copy of cGMP certificate of Drug Substance manufacturer of M/s Progress Life Sciences Pvt. Ltd., Unitissued by relevant regulatory authority III, Plot No. 23&24, Jawaharlal Nehru Pharma of country of origin shall be submitted City, Thanam (V), Parawada (M), J-311, Bhosari MIDC, Pune - 400 026 as the submitted GMP certificate is of Maharashtra, India issued by Food & Drugs different manufacturer Administration Maharashtra State India valid upto 13-06-2024 2.3.R.1 • Firm has submitted copy of Batch • Provide copy of Batch Manufacturing Manufacturing Record (BMR) for all the Record (BMR) for all the batches of drug product for which stability studies batches of drug product for which stability data is provided in Module 3 section studies data is provided in Module 3 section 3.2.P.8.3> 3.2.P.8.3> 3.2.S.4 • Drug substance manufacturer have • The firm submitted that as pregabalin was not claimed for EP specification while present in the old version of USP or BP, so the selected different limited of assay test API manufacturer had set the specifications as (95-105%) than EP monograph (98per EP general monograph and In-house 102%). Clarification is required specifications. Now the monograph of pregabalin is present in the USP and the • Clarification is required as drug material imported for product development substance manufacturer has claimed for EP specification while drug was according to USP specifications. The raw material specification of API is according to product manufacturer has claimed USP USP and the assay limit is 98% - 102%. The specifications and used different chromatographic conditions for assay results of API analysis were in concordant with both assay limits, i.e. (95%-105%) and (98%-102%). Clarification is required as drug substance manufacturer has submitted • As pregabalin was not present in the old specification as per EP while batch version of USP or BP, so the API manufacturer had set the specifications as per analysis as per USP general monograph and In-house • Clarification is required as drug product manufacturer has submitted specifications. Now the monograph of pregabalin is present in the USP and the limits of Enantiomeric purity as NMT material imported for product development 0.15% and results as 99.97% and was according to USP specifications. The Assay limits as 98.0-102% and results chromatographic conditions are same as complies in batch analysis 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 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) Dry Powder Injectable (Cephalosporin)	
3		

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-Kr. Sheikhupura Road, Faisalabad.	1			

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 07 th 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	
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	

	Stability studies Module-III (Drug Product):		verification, batch analysis and justification of specification, reference standard, container closure system and 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months. 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 equivious dissolution profile	ralence and comparative	Firm has submitted pharmac product against the product IM/IV by M/s Curexa He Laboratories Ltd.)	t Maxum 500mg Injection	
	Analytical method v product	validation/verification of	Firm has submitted method verification studies including specificity, linearity and range, accuracy, precision, detection limit, quantitation limit, system suitability.		
	l	STABILITY S	•		
Manu	facturer of API		Laboratories Limited., K4/4, Additional MIDC, At & Post ad, District: Raigad, Raigad 402302, Maharashtra India.		
API I	Lot No.	CEIV/B2012114			
	ription of Pack rainer closure system)	Filled and sealed glass vi	lled and sealed glass vial packed in unit carton.		
Stabi	lity Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	iency	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	
Manu	facturing Date	12-2021	12-2021	12-2021	
Date	of Initiation	09-02-2022	09-02-2022	09-02-2022	
No. o	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.	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		

			of M issue	has submitted copy of License retention certificate l/s Kopran Research Laboratories Limited., India., d by Food & Drugs Administration Maharashtra India valid upto 31-03-2025.
3.	approval from DRAP (in case of import).		VII(I API a mate studi	firm submitted Letter No. 10153/2020/DRAP-AD- (&E) dated 27-07-2020 for "permission to Import as per guidelines for import of pharmaceutical raw rial for the purpose of test/analysis and stability es" containing Cefepime HCl 02kgm issued by AD (a) DRAP Lahore
4.	attest chroi	ted respective documents like	attest	has submitted data of stability batches supported by ted respective documents like chromatograms, Raw sheets, COA, summary data sheets etc.
5.		pliance Record of HPLC software 21CFR dit trail reports on product testing	Not S	Submitted
6.	and l	ord of Digital data logger for temperature numidity monitoring of stability chambers time and accelerated)	Subn	nitted
Rema	arks o	f Evaluator ^{XI} :		
Sect	ion	Observations		Firm's Response
1.5.2		 The applied label claim shall include of description of dry powder injection of while for diluent separate registrate application shall be applied 	nly,	• 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 mentioned clearly, with comp 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		by	• 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.
3.2.9	5.4	 Copies of the Drug substance specification and analytical procedures used for row testing of the Drug substance by Droduct manufacturer is required. Analytical Method Verification studincluding specificity, accuracy repeatability (method precision) perform by the Drug Product manufacturer for disubstance shall be submitted. Justification is required for not perform test for Arginine content in batch analysis drug product manufacturer as recommend by drug substance manufacturer Justification shall be submitted for select the limit of water content test as 8.0%-11. in batch analysis instead of NMT 4.0 % drug product manufacturer as per disubstance manufacturer specifications 	tine brug dies and med lrug ning s by ded ting by	 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
3.2.1	P.8	• Clarification shall be submitted, as the basize mentioned in BMR is 500vials with 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

- 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 07 th 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 Cefepime1g Ampoule: Water for injection10ml
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-PE 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 a $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.
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.)
	Firm has submitted method verification studies

	product		including specificity, linear precision, detection limit, suitability.		
		STABILITY ST	TUDY DATA		
Manu	ufacturer of API		boratories Limited., K4/4, A District: Raigad, Raigad 402		
API I	Lot No.	CEIV/B2012114			
	ription of Pack tainer closure system)	Filled and sealed glass via	al packed in unit carton.		
Stabi	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 69^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 69^{\circ}$			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	nency	Accelerated: 0, 3, 6 (Mon Real Time: 0, 3, 6 (Month	•		
Batch	n No.	T-001	T-002	T-003	
Batch	n Size	500 vial	500 vial	500 vial	
Manu	ıfacturing Date	12-2021	12-2021	12-2021	
Date	of Initiation	09-02-2022	09-02-2022	09-02-2022	
No. o	of Batches		03		
		Administra	tive Portion		
2.	with stability study da Approval of API/ DM	L/GMP certificate of API	N/A Firm has submitted copy of cGMP certificate of M/s Kopran Research Laboratories Limited., K4/4,		
manufacturer issued by concerned regulatory authority of country of origin.		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/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 Nov VII(I&E) dated 27-07-2020 API as per guidelines for immaterial for the purpose of studies" containing Cefeping (I&E) DRAP Lahore	for "permission to Import port of pharmaceutical raw test/analysis and stability		
attested respective documents like		attested respective documents like chromatograms, Raw			
5.	Compliance Record of & audit trail reports of	f HPLC software 21CFR n product testing	Not Submitted		
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Submitted		
	arks of Evaluator XI:		T) •		
Sect	tion Observations		Firm's response		

1.5.2	• The applied label claim shall include only	• The firm submitted that our formulation is IV
	description of dry powder injection only,	Injection, the diluent used with injection is
	while for diluent separate registration	WFI. Registration letter of WFI is submitted
1.5.10	application shall be applied	0. 7. 1. 0. 1. 1.
1.5.10	• Dosage form of applied drug shall be	Sterile powder for injection
	mentioned clearly, with complete description of a unit	
1.6.5	Valid copy of cGMP certificate / DML of	• Firm has again submitted copy of License
1.0.5	Drug Substance manufacturer issued by	retention certificate of M/s Kopran Research
	relevant regulatory authority of country of	Laboratories Limited., K4/4, Additional MIDC,
	origin shall be submitted	Birwadi, Mahad-402302,, District: Raigad,
		India., issued by Food & Drugs Administration
2234		Maharashtra State India valid upto 31-03-2025.
3.2.S.4	• Copies of the Drug substance specifications	• Copies of the Drug substance specifications
	and analytical procedures used for routine testing of the Drug substance by Drug	and analytical procedures used for routine testing of the Drug substance by Drug Product
	Product manufacturer is required.	manufacturer is submitted.
	Analytical Method Verification studies	Analytical Method Verification studies is not
	including specificity, accuracy and	submitted
	repeatability (method precision) performed by the Drug Product manufacturer for drug	• As the material complies with USP
	substance shall be submitted.	specifications, arginine test is not performed in USP. That's why arginine test was not
	• Justification is required for not performing	performed by the manufacturer. USP
	test for Arginine content in batch analysis by	monograph is submitted
	drug product manufacturer as recommended	• The firm submitted that corrected limit is NMT
	by drug substance manufacturer	4% & revised COA is submitted
	• 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	
3.2.P.8	• Stability summary sheet for batch No#T-003	No reply submitted
	at real time conditions is not submitted	• The firm submitted that delay occurred due to
	• Justify the delay between manufacturing of	non-availability of reference standard for
	trial batches (12-2021) and initiation of	standardization of testing procedure
	stability studies (09-02-2022.).	• The firm submitted Letter No.
	• Submit AD (I&E) DRAP attested commercial invoice or clearance certificate	10153/2020/DRAP-AD-VIII(I&E) dated 27-07-2020 for "permission to Import API as per
	for the procurement of API.	guidelines for import of pharmaceutical raw
	Compliance Record of HPLC software	material for the purpose of test/analysis and
	21CFR & audit trail reports on product	stability studies" containing Cefepime HCl
	testing	02kg issued by AD (I&E) DRAP Lahore dated
	• Justify the results of assay test based on a	24-07-2020. However, no invoice or clearance
	single chromatographic area	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

- 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 27 th 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: Clotrimazole1%
	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 (r	ne-too status)	Clotri Lotion by M/s (Reg#88792)	Jawa Pharmaceuticals
Name and address of	f API manufacturer.	M/s Pranami Drugs Pvt. I Industrial Estate, Ankleshw Guj. India.	
Module-II (Quality	Overall Summary)	Firm has submitted QOS template. Summarized nomenclature, structure, gen physical form, manufarmanufacturing process and analytical procedures and its and justification of specific container closure system and substance and drug product its substance and drug product.	information related to heral properties, solubilities, cturers, description of d controls, specifications, everification, batch analysis cation, reference standard, and stability studies of drug
Module III (Drug Si	ubstance)	The firm has submitted detail general properties, solul manufacturers, description of controls, specifications, and verification, batch analyst specification, reference structure system and stability studies of	bilities, physical form, f manufacturing process and alytical procedures and its sis and justification of andard, container closure
Stability studies	Stability studies		study data of 3 batches of lerated as well as real time stability data is conducted at for 6 months. The real time $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH
Module-III (Drug P	roduct):	The firm has submitted description of manufacture specifications, analytical prestudies, batch analysis and preference standard, contains stability studies of drug productions.	ing process and controls, ocedure and its verification ustification of specification, iner closure system and
Pharmaceutical equidissolution profile	ivalence and comparative	Firm has submitted pharmac product against the pro GlaxoSmithkline Pak Limite	duct Stiemazol by M/s
Analytical method product	validation/verification of	Firm has submitted me including specificity, accura	
	STABILITY S	TUDY DATA	
Manufacturer of API	_	M/s Pranami Drugs Pvt. Ltd., Plot No. 7290 GIDC Industrial Estate 393002, Dist. Bharuch, Guj. India.	
API Lot No.	CLZ/0010221	CLZ/0010221	
Description of Pack (Container closure system)		ticolored 60ml labelled plastic bottle packed in unit carton	
Stability Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$	
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	CLT 22-151	CLT 22-152	CLT 22-153

Batch Size 150 Bottles			150) Bottles	150 Bottles	
Manufacturing Date 09-2022		_	2022	09-2022		
Date of Initiation 03-09-2022		_	09-2022	03-09-2022		
	No. of Batches			1 **	03	
			Administra	ative	Portion	
1.	Refe	rence of previous	approval of applications	Not s	submitted	
	 	<u>`</u>	ta of the firm (if any)			
2.	manı		L/GMP certificate of API by concerned regulatory f origin.	Not s	submitted	
3.			(in case of import).	for ir Bio-l	nport of 25kg of Clotrim	invoice dated 30-03-2021 nazole USP in name of M/s ed by AD (I&E) DRAP
			attest		ts like chromatograms, Raw	
5.		pliance Record o dit trail reports or	f HPLC software 21CFR	Subn	nitted	
6.	Reco	rd of Digital dat	ta logger for temperature ing of stability chambers	Subn	nitted	
I		f Evaluator XI:				
Sect 1.3.		• Submit copy of cGMP certificate / GMP		MP	Firm's response • Firm has submitted	copy of cGMP certificate
		inspection report of manufacturing un				based on inspection
1.5.	2	conducted with in last three years			conducted on 09-10-	
1.5.	2	Standardize your label claim in line w reference formulation		vitn	Clotrimazole Loti submission of fee. Each ml Contains: Clotrimazole	
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		by	• Firm has submitted c M/s Pranami Drugs GIDC Industrial E Bharuch, 393002, In	opy of cGMP certificate of Pvt. Ltd., Plot No. 7209 state, Ankleshwar, Dist. ndia, issued by Food & ninistration Gujarat State
3.2.		 Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. 		the	procedures used for a substance by Drug submitted.	rug substance analytical routine testing of the Drug substance manufacturer is
	• COA of primary / secondary reference standard including source and lot numb shall be provided.			lot number is submitt		
3.2.			or /	Compatibility studie with excipients is sub-	es of the Drug Substance omitted	

	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	submitted that it is	f specification you have stransparent solution while ied for topical lotion,	• 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	the number of un testing of drug pro	size of trial batches against nits required for complete oduct during stability study time stability study till	 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

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	
	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 27 th 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 USFD Approved Discontinued **Federal Register determination the product was not discontinued or withdrawn for safety 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#8374
Name and address of API manufacturer.	Envee Drugs Pvt. Ltd., N. H. No. 8, Dumral-387 35 Ta. Nadiad, Dist: Kheda, Gujarat, India
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-F template. Summarized information related nomenclature, structure, general properties, solubilities physical form, manufacturers, description manufacturing process and controls, specification analytical procedures and its verification, batch analyst and justification of specification, reference standar container closure system and stability studies of draubstance and drug product is submitted.
Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure general properties, solubilities, physical formanufacturers, description of manufacturing process are controls, specifications, analytical procedures and inverification, batch analysis and justification specification, reference standard, container closure system and stability studies of drug substance
Stability studies	Firm has submitted stability study data of 3 batches drug substance at both accelerated as well as real tin conditions. The accelerated stability data is conducted $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real tin stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ R for 48 months.
Module-III (Drug Product):	The firm has submitted detail of manufactured description of manufacturing process and control specifications, analytical procedure and its verification studies, batch analysis and justification of specification reference standard, container closure system as stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of the product against the product Momate 0.1% Lotion by Maxitech Pharma (Pvt.) Limited.

			specificity, linearity	and range, accuracy, precision suitability, robustness, Limit of	
	STABILITY STUDY DATA				
Manu	factu	rer of API	M/s Envee Drugs Pvt. Ltd Gujarat, India	l., N. H. No. 8, Dumral-	387 355, Ta. Nadiad, Dist: Kheda,
API L	Lot No).	EV/MF-072/19		
	-	n of Pack closure system)	A PVC bottle packed in r	nulticolored unit cartor	n
Stabil	ity St	orage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$		
Time	Perio	d	Real time: 6 months Accelerated: 6 months		
Frequ	ency		Accelerated: 0, 3, 6 (Mor Real Time: 0, 3, 6 (Mont		
Batch	No.		MOM22-127	MOM22-128	MOM22-129
Batch	Size		150 Bottles	150 Bottles	150 Bottles
Manu	factu	ring Date	08-2022	08-2022	08-2022
Date	of Init	tiation	27-08-2022	27-08-2022	27-08-2022
No. o	f Bato	ches		03	
			Administra	ative Portion	
1.			approval of applications ta of the firm (if any)	Not submitted	
2.			The firm has submitted copy of cGMP certificate of M/s Envee Drugs Pvt. Ltd., N. H. No. 8, at & postDumral-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).		(in case of import).	for import of 0.5kg of	of Mometasone Furoate USP in (Pvt.) Ltd attested by AD (I&E)
4.	attested respective documents like			cuments like chromatograms, Raw	
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)		ing of stability chambers	Submitted		
	Remarks of Evaluator XI:			Γ=.	
1.3.5 • Submit copy inspection rep		inspection rep	of cGMP certificate / GM ort of manufacturing ur in last three years		itted copy of cGMP certificate 3 based on inspection conducted
1.5.2	1.5.2 • Clearly indi		icate the Strength of Active Pharmaceutic	/ • The firm has	submitted label claim as per plation without submission of

	ingredient per unit in label claim along with submission of applicable fee	applicable fee. The applied label claim is as under:
	wasaa aa	Each gram contains: Mometasone furoate1mg
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 & postDumral-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

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 27 th 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 HCl1%
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 Pharmaceutical (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-PI 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 it verification, batch analysis and justification of specification, reference standard, container closur 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 a $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RI for 24 months.
Module-III (Drug Product):	The firm has submitted detail of manufacturers description of manufacturing process and controls

			specifications, analytical prostudies, batch analysis and jureference standard, contains stability studies of drug produces.	stification of specification, ner closure system and
	Pharmaceutical equividissolution profile	ralence and comparative	Firm has submitted pharmac product against the product Saffron Pharmaceutical Limit	t Terbisil Lotion by M/s
	Analytical method v product	validation/verification of	Firm has submitted method verification studies including specificity, linearity and range, accuracy, precision (repeatability), system suitability.	
	•	STABILITY S	ΓUDY DATA	
Man	ufacturer of API	M/s Shandong Boyuan P Development Zone, Jinar	harmaceutical Co., Ltd., Qiar n, Shandong, China	gjin Street, Jibei Economic
API	Lot No.	210617TA		
	ription of Pack tainer closure system)	Colorless clear solution i	n plastic bottle	
Stabi	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60^{\circ}$		
Time	e Period	Real time: 6 months Accelerated: 6 months		
Frequ	uency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batcl	h No.	TRB 22-145	TRB 22-146	TRB 22-147
Batcl	h Size	150 Bottles	150 Bottles	150 Bottles
Man	ufacturing Date	08-2022	08-2022	08-2022
Date	of Initiation	30-08-2022	30-08-2022	30-08-2022
No. o	of Batches		03	
	1		ative Portion	
1.	with stability study da	• • • • • • • • • • • • • • • • • • • •	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 Shandong Boyuan Pharmac Taixing East Street, Jibei Eco Jiyang District, Jinan City, issued by Center for A Pharmaceutical Profession A 06-05-2024	peutical Co., Ltd., No. 12 conomic Development Zone, Shandong Province, China assessment of Shandong
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 strattested respective document data sheets, COA, summary	s like chromatograms, Raw	
5.	Compliance Record of & audit trail reports of		Submitted	
6.		ta logger for temperature ing of stability chambers	Submitted	

(real	(real time and accelerated)			
Remarks o	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 HCl10mg 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,	Shandong Boyuan Pharmaceutical Co., Ltd.,
Andra Pradesh India whil API	Qianjin Street, Jibei Economic Development
manufacturer is M/s Shandong Boyuan	Zone, Jinan City, Shandong Province, China in
Pharmaceutical Co., Ltd., China.	name of M/s Bio-Labs (Pvt.) Ltd attested by AD
Clarification is required.	(I&E) DRAP Islamabad dated 30-07-2021.
• The batch No# of API (TBH-	Clearance certificate for same batch number API
II/00103/22) mentioned on clearance	is submitted
certificate is different than that submitted	
in batch analysis report of drug susbtance	

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.

submitted in the registration application.			
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 27 th 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 Dipropionate0.05% w/v		
Pharmaceutical form of applied drug	Lotion		
	Name, address of Applicant / Marketing Authorization Holder Name, address of Manufacturing site. Status of the applicant GMP status of the Finished product manufacturer Evidence of approval of manufacturing facility Status of application Intended use of pharmaceutical product Dy. No. and date of submission Details of fee submitted The proposed proprietary name / brand name Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		

Pharmacotherapeutic Group of (API)		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) Stability studies Module-III (Drug Product): Pharmaceutical equivalence and comparative dissolution profile		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	
			Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 60 months.	
			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.	
1 1			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 S		TUDY DATA	
Manuf	facturer of API	M/s Anuh Pharma Ltd., Turbhe, Navi Mumbai-40	Plot No. D-5/8 & 5/9, T.T.C. Industrial Area, M.I.D.C., 00703 India	
API L	API Lot No. APL/01081/C-20			
	Description of Pack (Container closure system) Colorless clear solution i		n plastic bottle	

Stability Storage Condition		orage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Period		d	Real time: 3 months Accelerated: 3 months		
Frequ	uency		Accelerated: 0, 3 (Month Real Time: 0, 3 (Months)	The state of the s	
Batcl	h No.		BTN 22-148	BTN 22-149	BTN 22-150
Batcl	h Size		150 Bottles	150 Bottles	150 Bottles
Man	ufactu	ring Date	08-2022	08-2022	08-2022
Date	of Init	tiation	31-08-2022	31-08-2022	31-08-2022
No. o	of Bato	ches		03	,
			Administra	ntive Portion	
1.			approval of applications ta of the firm (if any)	Not submitted	
2.			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.	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.		
attested respective documents like		e documents like w data sheets, COA,	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		
5.		pliance Record of dit trail reports or	f HPLC software 21CFR n product testing	Submitted	
6.	and 1	-	ta logger for temperature ing of stability chambers ated)	Submitted	
Rem	arks o	of Evaluator ^{XI} :	1		
	tion	Observations		Firm's Response	
1.3.	5	inspection rep	of cGMP certificate / GMP ort of manufacturing unit h in last three years	• Firm has submitted codated 28-12-2023 based on 09-10-2023.	py of cGMP certificate on inspection conducted
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 reference formulation applicable fee. The application application application is the submitted of the submitted reference formulation applicable fee. The application is the submitted feet and submitted reference for the submitted reference for the submitted feet and submit	without submission of ed label claim is as under:
1.6.5		 Walid copy of of Drug Subst by relevant country of orig Address of AP 	dress of Drug substance shall be submitted cGMP certificate / DML ance manufacturer issued regulatory authority of gin is required I manufacturer mentioned S.2 is different than that	 M/s Anuh Pharma Ltd. North Wing, Dr. Annie 400018, India The firm has submitted of M/s Anuh Pharma Ltd. North Wing, Dr. Annie 400018, Dist-Mumbai 	, 3-A, Shivsagar Estate, Besant Road, Mumbai-

	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

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 27 th 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 Phosphate1% 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 Pharmaceutica (Reg#109424)
Name and address of API manufacturer.	M/s Zhejiang Hisoar Chuannan Pharmaceutical Co Ltd., No.23, Donghai 5 th Ave., Zhejiang Chemic Materials Base Linhai Zone, Linhai City, Zhejian Province, China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-P template. Summarized information related nomenclature, structure, general properties, solubilities physical form, manufacturers, description manufacturing process and controls, specification analytical procedures and its verification, batch analyst and justification of specification, reference standar container closure system and stability studies of drusubstance and drug product is submitted.
Module III (Drug Substance)	The firm has submitted detail of nomenclature, structur general properties, solubilities, physical form manufacturers, description of manufacturing process are controls, specifications, analytical procedures and i verification, batch analysis and justification especification, reference standard, container closur system and stability studies of drug substance
Stability studies	Firm has submitted stability study data of 3 batches drug substance at both accelerated as well as real tin conditions. The accelerated stability data is conducted $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real tin stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ R for 36 months.
Module-III (Drug Product):	The firm has submitted detail of manufacturer description of manufacturing process and control specifications, analytical procedure and its verification studies, batch analysis and justification of specification reference standard, container closure system are stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of the product against the product Dalacin T 1% Lotion by M Pfizer Pakistan Ltd.
Analytical method validation/verification of product	Firm has submitted method verification studi- including specificity, linearity and range, accurac precision (repeatability), system suitability.

	STABILITY STUDY DATA				
Manu	M/s Zhejiang Hisoar Chuannan Pharmaceutical Co., Ltd., No.23, Donghai 5 Ave., Zhejiang Chemical Materials Base Linhai Zone, Linhai City, Zhejian Province, China				
API I	Lot No.	P-006-CN20211221			
	ription of Pack tainer closure system)	A multicolored 30ml labe	elled plastic bottle pack in un	it carton	
Stabi	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	nency	Accelerated: 0, 3, 6 (Mor Real Time: 0, 3, 6 (Mont	The state of the s		
Batch	n No.	CLD 22-171	CLD 22-172	CLD 22-173	
Batch	n Size	150 Bottles	150 Bottles	150 Bottles	
Manu	facturing Date	09-2022	09-2022	09-2022	
Date	of Initiation	04-09-2022	04-09-2022	04-09-2022	
No. o	f Batches		03		
		Administra	ative Portion		
1.	Reference of previous with stability study da	approval of applications ta of the firm (if any)	Not submitted		
manufacturer issued by concerned regulatory authority of country of origin.		Firm has submitted copy of active substance exported to Chuannan Pharmaceutical C Ave., Zhejiang Chemical M Linhai City, Zhejiang Provin 2025. The certificate states complies with the requir Manufacturing Practice. The firm has submit (License#ZHE20110004) of Chuannan Pharmaceutical C Avenue., Zhejiang Chemic Zone, Zhejiang, China valid	EU of M/s Zhejiang Hisoar o., Ltd., No.23, 5 th Donghai laterials Base Linhai Zone, nce, China valid upto 06-03-s that manufacturing plant ement of Chinese Good tted copy of DML of M/s Zhejiang Hisoar o., Ltd., No.23, 5 th Donghai al Materials Base Linhai		
3. Documents for the procurement of API with approval from DRAP (in case of import).		Firm has submitted copy of 25-07-2022 for import o Phosphate USP in name of attested by AD (I&E) DRA 2022.	f 05kg of Clindamycin M/s Bio-Labs (Pvt.) Ltd		
		Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Ray data sheets, COA, summary data sheets etc.			
5.	Compliance Record of & audit trail reports of	f HPLC software 21CFR n product testing	Submitted		
6.	and humidity monitor (real time and accelera	ta logger for temperature ing of stability chambers ated)	Submitted		
	Remarks of Evaluator XI:				
Sect	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
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.

Each ml Contains:

Clindamycin Phosphate eq. to Clindamycin10mg

- 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 Poad Islamahad
Charles of the court of	Triangle, Kahuta Road, Islamabad.
Status of the applicant	⊠ Manufacturer
	☐ Importer☐ Is involved in none of the above (contract giver)☐
CMD status of the Einighed and dust	
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-L (Vol-IV) dated 27 th September 2021 specifying Lotic (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 Acetonide0.01%
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% USFD Approved
For generic drugs (me-too status)	Oleofin 0.01% Oil (Topical Oil) by M/s Derma Techi Pakistan (Reg#111740)
Name and address of API manufacturer.	M/s Tianjin Tianyao Pharmaceuticals Co., Ltd., No. 1 Xin Ye 9 th street, West Area of Tianjin Economi Technological Development Area, Tianjin 30046 China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-P template. Summarized information related nomenclature, structure, general properties, solubilities physical form, manufacturers, description manufacturing process and controls, specification analytical procedures and its verification, batch analyst and justification of specification, reference standar container closure system and stability studies of drusubstance and drug product is submitted.
Module III (Drug Substance)	The firm has submitted detail of nomenclature, structur general properties, solubilities, physical formanufacturers, description of manufacturing process are controls, specifications, analytical procedures and i verification, batch analysis and justification

			specification, reference sta system and stability studies of	*
	Module-III (Drug Product):		Firm has submitted stability drug substance at both acce conditions. The accelerated s $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH stability data is conducted at for 60 months.	lerated as well as real time stability data is conducted at for 6 months. The real time
			The firm has submitted description of manufacturi specifications, analytical prostudies, batch analysis and jureference standard, contains stability studies of drug productions.	ing process and controls, ocedure and its verification ustification of specification, iner closure system and
	Pharmaceutical equiv dissolution profile	ralence and comparative	Firm has submitted pharmaceutical equivalence of their product against the product Derma Smooth by M/s Valor Pharmaceutical.	
	Analytical method v product	ralidation/verification of	Firm has submitted method specificity, linearity and repeatability), system suita detection and quantitation lin	range, accuracy, precision bility, robustness, limit of
		STABILITY S	ΓUDY DATA	
Manu	facturer of API		armaceuticals Co., Ltd., No. nic-Technological Developm	
API I	Lot No.	NES211113		
Descr (Cont	ription of Pack ainer closure system)	A muticolored 120ml la leaflet	belled plastic bottle pack in	unit carton with enclosed
Stabil	ity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60^{\circ}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequ	ency	Accelerated: 0, 3, 6 (Mon Real Time: 0, 3, 6 (Mont	· · · · · · · · · · · · · · · · · · ·	
Batch	No.	FLU 22-134	FLU 22-135	FLU 22-136
Batch	Size	150 Bottles	150 Bottles	150 Bottles
Manu	facturing Date	10-2022	10-2022	10-2022
Date	of Initiation	09-10-2022	09-10-2022	09-10-2022
No. o	f Batches		03	
	Administrative Portion			
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.		The firm has submitted copy Pranami Drugs Pvt. Ltd., Plo Estate, Ankleshwar, Dist. I Food and Drugs Control A India valid till 19-08-2024	ot No. 7290 GIDC Industrial Bharuch, India, issued by
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Firm has submitted copy of 14-05-2022 for import of	

			Acetonide USP in name of M/s Bio-Labs (Pvt.) Ltd attested by AD (I&E) DRAP Islamabad dated 14-05-2022.	
attested respective documents like		attes	has submitted data of stability batches supported by ted respective documents like chromatograms, Raw sheets, COA, summary data sheets etc.	
5.		pliance Record of HPLC software 21CFR dit trail reports on product testing	Subr	nitted
6.	and 1	ord of Digital data logger for temperature humidity monitoring of stability chambers time and accelerated)	Subr	nitted
Rema	arks o	of Evaluator ^{XI} :		
Sect		Observations		Firm's Response
1.3.		• Submit copy of cGMP certificate / C inspection report of manufacturing 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.		 Standardize your label claim in line reference formulation along with submis of applicable fee 	sion	• The firm has submitted the label claim for Flucin Topical Oil 0.01% w/v without submission of fee. Each ml Contains: Fluocinolon Acetonide0.1mg However the reference product recommends label claim in w/w units.
1.5.	10	You have applied for lotion while 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 / DMI Drug Substance manufacturer issued relevant regulatory authority of countr origin is required GMP certificate of a different manufact is submitted than that the details dat which is submitted in this section an module 3 	by y of turer a of	^ ·
3.2.	S.5	 COA of primary / secondary references standard including source and lot nur shall be provided. 		
3.2.	S.7	Submit stability study data of drug substate as per zone IV-A conditions till clair shelf life		
3.2.	P.8	Raw data sheets of drug product at ir time point of stability study shall	nitial	Raw data sheets of drug product at initial time raint of otability study is submitted.

submitted

time point of stability study shall be

- 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)

point of stability study is submitted

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 13 th 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 erythromycin200mg
	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 A	Module-II (Quality Overall Summary) I I I I I I I I I I I I I I I I I I I		ailand) Ltd., 309, Bangpoo Sukhumvit Road, Moo 4, pur Muangsamutprakan, nd
Module-II (Quality O			as per WHO QOS-PD information related to eral properties, solubilities, cturers, description of d controls, specifications, verification, batch analysis cation, reference standard, and stability studies of drug s submitted.
Module III (Drug Sub			of nomenclature, structure, bilities, physical form, of manufacturing process analytical procedures and lysis and justification of andard, container closure of drug substance
Stability studies			study data of 3 batches of lerated as well as real time stability data is conducted at for 6 months. The real time $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH
Module-III (Drug Pro			detail of manufacturers, ng process and controls, ocedure and its verification astification of specification, ner closure system and act.
Pharmaceutical equiving dissolution profile	alence and comparative	Firm has submitted pharmac product against the product suspension.	•
Analytical method v	ralidation/verification of	Not submitted	
	STABILITY S	TUDY DATA	
		(Thailand) Ltd., 309, Bangpo o 4, Tumbol Phraksa, A ailand	
API Lot No.	EES/M-002/22		
Description of Pack (Container closure system)	White color labeled card	board box contains labeled an	nber plastic bottle
Stability Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Time Period	Time Period Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Monte Real Time: 0, 3, 6 (Monte	· ·	
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			1	03		
			Administr	ative	Portion	
1.			as approval of applications ata 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.		Lina Indus Tum Samu Adm certis reliec 2022	ria Chemicals strial Estate So bol Phraksa, atprakan, 10280, inistration, Minificate states that d upon to reflect to	copy of cGMP certificate of M/s (Thailand) Ltd., 309, Bangpoo i 6C, Sukhumvit Road, Moo 4, Ampur Muangsamutprakan, Thailand., issued by Food & Drugs stry of Public Health Thailand. The the manufacturing site should be the compliance status until 17 th June tificate is further extended to 17 th		
3.	Documents for the procurement of API with approval from DRAP (in case of import).		13-10 name salt a	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.	attes	ted respectiv	ms, Raw data sheets, COA, COA, s			locuments like Raw data sheets,
5.			of HPLC software 21CFR on product testing		ficate of Complitited	iance of HPLC software 21CFR is
6.	and		ata logger for temperature oring of stability chambers rated)	Not s	submitted	
Rem	arks o	of Evaluator XI:				
	tion	Observations			Firm's respon	
1.3.		inspection r conducted wi	y of cGMP certificate / Ceport of manufacturing th in last three years	unit	The Addition Islamabad da cGMP certific	
Valid copy of cGMP certificate / DMI Drug Substance manufacturer issued relevant regulatory authority of country origin shall be submitted		by y of	certificate of Ltd., 309, Ba Sukhumvit F Ampur Mu 10280, Thail Administration Thailand. Thailand Thail			
Your applied formulation contains the safety form "Erythromycin Ethylsuccinate" why you have submitted data of "Erythromycstearate" drug substance. Clarification		vhile ycin	module w	bmitted that by mistake wrong as attached. Erythromycin e is used in applied formulation		

	required for further processing of application whether same salt form of substance was used in applied produc otherwise	drug et or
3.2.S.4	 Copies of the Drug substance specifica and analytical procedures used for rottesting of the Drug substance by Product manufacturer is required. Justification shall be submitted for selections for drug substance by substance manufacturer and submit batch analysis of drug substance as per specifications by both drug substance manufacturer and drug product manufacturer and drug product manufacturer. 	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
3.2.P.2	Compatibility studies of the Drug Subst with excipients shall be provided as qualitative composition of the formulatinot similar to innovator / reference prodes and the product of the formulatinot similar to innovator / reference prodes and the product of the formulatinot similar to innovator / reference prodes and the formulatinot similar to innovator / reference prodes and the formulatinot similar to innovator / reference prodes and the formulatinot similar to innovator / reference prodes and the formulatinot similar to innovator / reference prodes and the formulatinot similar to innovator / reference prodes and the formulatinot similar to innovator / reference prodes and the formulatinot similar to innovator / reference prodes and the formulation of the f	• 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 Applied product Erythromycin ethyl succinate Granules for Oral Susp.
3.2.P.5	 Analytical method for assay test (microassay) for applied product is not submit Analytical method verification report assay test is not submitted 	ed antibiotics is submitted
3.2.P.8	• Date of initiation and implementation	while sheet. The date of initiation of stability was 27- 12-2022 which is also mentioned on the
	• Clarification is required since the in date of drug substance as per submodelearance certificate (13-10-2023) subsequent to the manufacturing date 2022) of trial batches (as per submitted by	that's why there was difference in dates. New invoice is submitted. (12- • Firm has submitted copy of commercial invoice

analysis report, BMR and stability summary	EES/M-002/22) in name of M/s Shaigan	
sheets)	Pharmaceuticals. However invoice is not	
• The batch number of API in clearance	attested by AD (I&E) DRAP.	
certificate is different than that given in		
submitted dossier, clarify		
Raw data sheets including calculation details	• Raw data sheets including calculation details	
for assay test is not submitted	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	

- 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

• Stabi	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	

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 Dist502291 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	Y DATA		
Sangareddy Dist5022					
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)			
•			White color labeled cardboard box contain 1x10 labeled aluminum achet, 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			
		Real time: 6 months Accelerated: 6 months			
		Accelerated: 0, 3, 6 (MoReal Time: 0, 3, 6 (Mo	•		
Batch No	О.	T-001	T-002	T-00.3	
Batch Si	ze	500 sachet	500 sachet	500 sachet	
Manufacturing Date		06-2022	06-2022	06-2022	
Date of I	nitiation	28-06-2022	28-06-2022	28-06-2022	
No. of B	atches		03		
		Administrative Po	ortion		
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).		Not submitted		
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.		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 HI audit trail reports on prod		

		,	
6.	Record of Digital data logger for temperature and		
	humidity monitoring of stability chambers (real time and accelerated) humidity monitoring of stability chambers (real time and accelerated) is submitted		
	s of Evaluator XI:		
Section			
1.3.4	Submit copy of valid Drug Manufacturing Lice		
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 soc 	lium 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		dard for omeprazole including source and lot	
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			
3.2.P.6	8		
3.2.P.8	provided.Detailed raw data sheet for stability testing is	not submitted	
3.2.1.0			
 UV absorbance value or spectra for dissolution testing is not submitted in sta Submit documents for the procurement of API with approval from DRAP (in 		• • • • • • • • • • • • • • • • • • • •	
D		**	
	: Registration Board deferred the case for submis		
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	

Firm has submitted copy of letter No. F.1-18/92- Lic (Vol-III) dated 13-01-2022 specifying Sachet Section (General) New.
☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
☐ Domestic sale ☐ Export sale ☑ Domestic and Export sales
Form-5F Dy.No 17573 dated 13-07-2023
Rs.30,000/- dated 20-06-2023 Deposit slip#307907903)
yber 40mg Sachet
Each Sachet Contains: Dimeprazole
Powder for oral suspension
Proton Pump Inhibitor
nnovator's specifications
x10 sachet
As per SRO
ZEGERID OTC (20mg/packet; 1.68gm/packet, 0mg/packet; 1.68gm/packet) for Oral Suspension USFDA Approved
Risek Insta Sachet 40mg + 1680mg by M/s Getz Pharma (Reg# 58548)
Omeprazole: M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist502291 Telangana India
Firm has submitted QOS as per WHO QOS-PD emplate. Firm has summarized information elated to nomenclature, structure, general properties, solubilities, physical form, nanufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and statistication of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Firm has submitted detailed drug substance data elated to nomenclature, structure, general properties, solubilities, physical form, nanufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and ustification of specification, reference standard, container closure system and stability studies of lrug 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 $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $05 \pm 3^{\circ}\text{C}$ for 36 months.	
Module-III (Drug Product):		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability 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	Y DATA	
		_	s limited., Aroor Village, Sadasivapet Mandal, 291 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)		
1		White color labeled cardboard box contain 1x10 labeled aluminum sachet, filled with shite, mint flavored powder for oral suspension.		
3 0		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period Real time: 6 months Accelerated: 6 months				
Frequen	cy	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)	
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).	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 & Compliance Record of HPLC software audit trail reports on product testing audit trail reports on product testing is	
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	s of Evaluator ^{XI} :	
Section	Observations	
1.3.4	Submit copy of valid Drug Manufacturing Lic	
1.3.5	three years	port of manufacturing unit conducted with in last
1.6.5		ance manufacturer for omeprazole and sodium
1.5.6	 bicarbonate issued by relevant regulatory authority of country of origin is required You have applied for innovator's specifications while the applied product is available in clarify 	
3.2.S		
Copies of the Drug substance analytical procedures used for routine testing of substance omeprazole by Drug substance manufacturer and drug product manufactured. Provide COA of relevant batch of Drug Substance omeprazole from Drug		anufacturer and drug product manufacturer is Substance omeprazole from Drug substance
3.2.S.5		
3.2.P.1	number shall be provided. 1 • Justification is required as you have mentioned the use of sodium bicarbonate as inactiving ingredient (buffer), while innovator product review document uses it as the active ingredie in the formulation	
3.2.P.5		
3.2.P.6		
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). 	

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 18 th 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: Simethicone125mg	
	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 (m	e-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 C	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 Sul	ostance)	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 E (Conditions & duration)	orug Substance on of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} \ / \ 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} \ / \ 65\% \pm 5\%$ RH for 24 months.	
Module-III (Drug Pro	oduct):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
Pharmaceutical Equi Dissolution Profile	valence and Comparative	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 product	validation/verification of	Firm has submitted method validation studies including accuracy, precision (repeatability, intermediate), linearity, range, robustness, specificity, detection limit, quantitation limit.	
1	STABILITY ST	UDY DATA	
Manufacturer of API	_	icals Private Limited., 129/1/A, 129/12, 13, 14, 15, ri- 391 340. Vadodara, Gujarat, India	
API Lot No.	17/G/SI/001		
Description of Pack Container closure system)	ALU/PVC Blister Packs box.	ALU/PVC Blister Packs along with the Package Inserts are packed in a carton box.	
tability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$	$5\% \pm 5\% RH$	

		Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$	/ 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	О.	TF-01	TF-02	TF-03
Batch Siz	ze	1000 Capsule	1000 Capsule	1000 Capsule
Manufac	turing Date	02-2018	02-2018	02-2018
Date of I	nitiation	02-2018	02-2018	02-2018
No. of B	atches		03	
		Administrativ	ve 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 290 th meeting dated 3 rd - 4 th July, 2019 decided to approve registration of Rofair 500mcg tablet. Inspection date: 25 th 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.			vate Limited., 129/1/A, & POST Nandesari- Dist- v Food & Drugs Control
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Firm has submitted copy of import of Simethicon USP Kaizan Pharmaceuticals atte Karachi dated 14-11-2017.	1.505 kg in name of M/s
4.			Firm has submitted dat supported by attested respectate data sheets, and summary data	ctive documents like Raw
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		testing	
6.	and humidity monitoring of stability chambers (real time and accelerated)			pility chambers (real time
	s of Evaluator XI:			
1.5.6 1.6.5	1.5.6 • You have applied for innovator's specifications while the applied product is available in USP, clarify			·

3.2.S.4	• Justification shall be submitted for not including the test for Contest of Ciliago Dismide in	ī
3.2.3.4	• 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	
2255	batch analysis of drug substance by drug product manufacturer	4
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be	
22.0.0	provided.	4
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	
2255	applied product is not similar to reference product	4
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: R	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; Cholecalciferol5mg (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.
	(Conditions & duration of Stability studies) Module-III (Drug Product): Pharmaceutical Equivalence and Comparative Dissolution Profile		Firm has submitted stability of drug substance at both actime conditions. The acce conducted at 25°C ± 2°C months. The real time stability 5°C ± 3°C for 06 months.	y study data of 3 batches eccelerated as well as real elerated stability data is / 60% ± 5% RH for 6
			Firm has submitted data of of description, compositing development, manufacture, and process control, process control of excipients, conspecifications, analytical panalytical procedures, batch specifications, reference container closure system and	on, pharmaceutical manufacturing process ess validation protocols, ntrol of drug product, rocedures, validation of analysis, justification of standard or materials,
			Firm has submitted pharm their product against the proby M/s Neutro Pharma.	
	Analytical method validation/verification of product		Firm has submitted met including specificity, line precision (repeatability, in LOD, LOQ.	earity, range, accuracy,
	1	STABILITY ST	UDY DATA	
Chang			uxin Pharmaceutical Co., Lto nomic Development (south	
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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Per	riod	Real time: 03 months Accelerated: 03 months		
Frequency		Accelerated: 0, 3 (Month Real Time: 0, 3 (Months)		
Batch No	0.	D-T2	D-T3	D-T4
Batch Si	ze	1000 Ampoule	1000 Ampoule	1000 Ampoule
Manufac	cturing Date	08-2023	08-2023	08-2023
Date of l	Initiation	28-08-2023	28-08-2023	28-08-2023
No. of Batches			03	
		Administrativ	ve 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 (DML#20160429) of M/s of Pharmaceutical Co., Ltd., Changjiang Road, Econom district), Shifang City, Si	Sichuan Province Yuxin No.51 west section of nic Development (south

	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 & Submitted & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) Submitted
Remark	s 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	M/s Fynk Pharmaceuticals, 19 km, G.T. Road,
	Authorization Holder	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 c	ontrols, tests for impurity
		& related substances, sprocedures and its verification 0422043, mfg. date 04-20 specification, working start system and stability studies of	on, batch analysis (ASS-22) and justification of dard, container closure
Stability Studies of Drug (Conditions & duration of		Firm has submitted stability drug substance at both accelerated stability at 40°C \pm 2°C / 75% \pm 5% R time stability data is conducted to the stability	erated as well as real time tability data is conducted $\pm H$ for 6 months. The real ted at 30°C \pm 2°C / 65%
Module-III Drug Produc	t:	Firm has submitted data of description, compositidevelopment, manufacture, and process control, procecontrol of drug product, sprocedures, validation of an analysis, justification of standard or materials, contastability.	on, pharmaceutical manufacturing process sess validation protocols, specifications, analytical alytical procedures, batch specifications, reference
Pharmaceutical Equival Dissolution Profile	ence and Comparative	Firm has submitted pharmatheir product against Ampidinjection, manufactured by Chealth products, batch No. 22 by performing quality test placentent, assay and sterility.	cillin sodium 500mg for Chongquing medicine and 11028, mfg. date 10-2021
Analytical method va	lidation/verification of	Firm has submitted analytica reports for drug substance as	
	STABILITY ST	UDY 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 re	ubber stopper and aluminium	flip of seal.
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time Period.	Real time: 6 months Accelerated: 6 months		
Frequency.	Accelerated: 0, 3, 6 (Mor Real Time: 0, 3, 6 (Mor		
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 A	LONG 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.	
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.	
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)	

Remarks of Evaluator:

Sr.	ks of Evalu	Observation	Reply by the firm	
No.	Section	Observation	Kepiy 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.	

	Τ.
Justify the submitted chromatograms	Fi
with respect to BP monograph	inj
wherein it is mentioned that "the	the
assay is not valid unless, in the	Ar
chromatograms obtained with	the
solution (3), the resolution peaks	Th
between the peaks due to ampicillin	chi
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	Αŗ
applications with studinty study data	T.

submitted.

of the firm (if any) shall be

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 $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 60months. Accelerated stability conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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

1.	1.6.5 Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.						
Sr. No.	Section	Observatio	n	I	Response	by the firm	
Remar	time and ac						
6.	Record of Digital data logger for temperature an humidity monitoring of stability chambers (rea				Submitte	ed.	
5.		e Record of reports on pro	HPLC software 21CFR & duct testing	& Submitted.			
4.	attested res Raw data s	spective documents, COA,	nes will be supported by ments like chromatograms summary data sheets etc.	,	Submitte		
3.	approval fr	om DRAP (i	rocurement of API with a case of import).	PL/P-INV/HO/866 have purchased 1kg M/s Pharmagen Lim not mentioned any b date of the drug subs	dated 03- g of Amp nited. Ho patch num stance.	-01-2022 whe bicillin trihydrowever, the invaluer and manu	rein they ate from voice has
2.	manufactu		by concerned regulatory	Copy of GMP certificate No. 06/2019-DRAF (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted.			
1.			approval of application of the firm (if any)	Not submitted.			
	DOCUME	NTS / DATA	TO BE PROVIDED AI	ONG WITH STABILITY STUDY DATA			
	Batches			03		30 32 20	
	f Initiation		08-02-2022	08-02-2022		08-02-202	
Batch S	Size acturing Date		2000 Capsules 02-2022	2000 Capsules 02-2022		2000 Caps 02-2022	
Batch 1			A	B 2000 Consular		2000 Cara	1
Freque			Accelerated: 0, 3, 6 (Mon Real Time: 0, 3, 6 (Mont	hs)			
Time F	Period		Real time: 6 months Accelerated: 6 months				
-	ty Storage Con	•	printed Alu - Alu blister Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$	5% ± 5% RH	раскей п	ir unit carton.	
	ot No. ption of Pack iner closure sy	votom)	Almost white granular printed Alv. Alv. blisten				acked in
	acturer of API	[M/s Pharmagen Limited Lahore.	l, Kot Nabi buksh w	vala, 34	K.M. Ferozpi	ır Road,
			STABILITY STU	JDY DATA			
Analytical method validation/verification				Firm has submitted and reports for drug substa			
						, mfg. da , Pakistan i l.5 & 6.8. valu	in three

2.	2.3	Table for literature references with correct information	
	2225	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	
٠.		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 	
,.	3.2.1 .3.3	method verification studies of 250mg capsule for	
		500mg capsule.	
		<u> </u>	
		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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 36 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ 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 ST	UDY DATA		
Manufa	cturer of AP	I	Vartika Chemicals & Pharmaceuticals Pvt. Ltd., G1-567, RIICO Industrial Area, Khushkhera, Bhiwadi – 301019 Dist. Bhiwadi (Rajasthan), India.			
API Lot	t No.		AMX-0422060.			
Description of Pack (Container closure system)		Type II glass vial with r	ubber stopper and aluminum fl	lip of seal.		
Stability	y Storage Co	ndition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time Pe	eriod		Real time: 06 months Accelerated: 06 months			
Frequen	ncy		Accelerated: 0, 3, 6 (Mor Real Time: 0, 3, 6 (Mor			
Batch N	lo.		T-001	T-002	T-003	
Batch S	ize		300 vials	300 vials	300 vials	
Manufa	cturing Date		11-2022	11-2022	11-2022	
Date of	Initiation		16-11-2022	16-11-2022	16-11-2022	
No. of I	Batches			03	I	
			Administrativ	e Portion		
1.			approval of applications 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).			6893/2022DRAP (E-139352) 2022 mentioning 1kg of Am (BP) with batch No. AMX-4	0227361) dated 07-06-oxicillin Sodium sterile 22060, mfg. date of 30-artika Chemicals & dia attested by Assistant	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			Submitt	ed	
5.	•	e Record of Feports on pro	IPLC software 21CFR & duct testing	Submitt	ed	
6.			Submitt	ed		
	ks of Evalua			D 1 1 4 6		
Sr. No.	Section	Observatio	n	Reply by the firm		
1.	1.6.5		of the GMP certificate of ostance manufacturer shall d.	certificate No. 01761/GMP/2023/4069 dat issued by Food Safety and	drugs control ernment of	

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.	3.24.3	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.
	Each capsule contains: Fluconazole
	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.
	Flucoz 150mg Capsule, Albro Pharmaceutical, Reg. No 067807.
	M/s Hema Pharmaceuticals (Pvt.) Ltd., Plot No 6201/A&B, GIDC Estate, Opposite EWAC Alloy Ltd. Ankleshwar, Gujrat, India.
	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.
	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)	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 60 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 06 months Batches: (12PDFC001, 12PDFC002 & 12PDFC003)
	Firm has submitted details of the drug product including its description, composition, pharmaceutica 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, contained closure system and stability.

			innovator product i.e. Diffu 1890017, mfg. date 08-2020 I Identification, weight variat Dissolution & Assay. Results innovator product are comparate Comparative Dissolution is a same product i.e. Diflucan ca 1.2), Acetate buffer (pH 4.5) 6.8). Values of F ₂ are in accep	by performing quality tests tion, disintegration time, of both the test product and able. also performed against the apsule in Acid media (pH & Phosphate Buffer (pH
	Analytical method validat product	tion/verification of	Method verification studies System suitability, specificity,	
		STABILITY	STUDY DATA	
Manufac	cturer of API		nceuticals (Pvt.) Ltd., Plot No. Alloy Ltd., Ankleshwar, Gujrat	
API Lot	No.	21FC0001.		
	tion of Pack ner closure system)	White to off white	powder filled in Blue/blue hard	l gelatin capsule shell.
Stability	Storage Condition		2°C / 65% ± 5%RH ± 2°C / 75% ± 5%RH	
Time Pe	eriod	Real time: 6 month Accelerated: 6 mon		
Frequen	icy	Accelerated: 0, 3, 6 Real Time: 0, 3, 6		
Batch N	0.	T001	T002	T003
Batch Si	ize	1000 Capsules	1000 Capsules	1000 Capsules
Manufac	cturing Date	08/2022	08/2022	08/2022
Date of	Initiation	18/08/2022	19/08/2022	20/08/2022
No. of B	Batches		03	
	DOCUMENTS / DATA T	O BE PROVIDED	ALONG WITH STABILIT	Y STUDY DATA
1.	Reference of previous applications with stability firm (if any)		Not Subr	nitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			GMP certificate for M/s
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Firm has submitted copy of in 03-02-2021 mentioning 50kg of 21FC0001, mfg. date 01-2021 pharmaceutical Lahore. Invoi Director, DRAP, Lahore dated Firm has also submitted Fluconazole from M/s Wimits	of Fluconazole USP, B. No. in the name of M/s Wimits ce is attested by Assistant 108-03-2021.
4.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Submi	tted
5.	Compliance Record of 21CFR & audit trail reports		Not subn	nitted.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Submitted
Remark	ks of evaluat	· · · · · · · · · · · · · · · · · · ·	
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		Firm has submitted new COA for the drug substance from drug substance manufacturer. However, in the initially submitted COA results were over written. 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. 	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. 	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.
		• 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.	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
		Submitted chromatograms does not reflect any wave length. Justification shall be submitted.	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
		Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	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.
		• 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.

• 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 valida submitted in the registration application.	thon of first time batches as per the communication
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
<u>-</u>	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
	Pharmacotherapeutic Group of (API)	Other antibacterial (J01XX)
-		
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmaceutical form of applied drug Reference to Finished product specifications	Film coated tablet. USP specification.
	Reference to Finished product specifications	USP specification.
	Reference to Finished product specifications Proposed Pack size	USP specification. As per SRO/DPC.
	Reference to Finished product specifications Proposed Pack size Proposed unit price	USP specification. As per SRO/DPC. As per SRO/DPC. ZYVOX® (linezolid) 400mg tablets, USFDA approved. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness
	Reference to Finished product specifications Proposed Pack size Proposed unit price The status in reference regulatory authorities	USP specification. As per SRO/DPC. As per SRO/DPC. ZYVOX® (linezolid) 400mg tablets, USFDA approved. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**

		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 Substand	ce)	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 (Conditio Stability studies)	ns & duration of	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 60 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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 dissolution profile	ce and comparative	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 validati product	on/verification of	Method verification studies are submitted including System suitability, specificity, accuracy, precision.
	STABILITY	STUDY DATA
Manufacturer of API		tories Private Limited, Survey No. 145/A, 145/AA & 147, (V), Bommala ramaram (M), Yadadri — Bhuvanagiri langana, India.
API Lot No.	OT-LID/12/20/048	3.
Description of Pack	Alu/Alu Blister 0f	2 x 7's tablets with leaflet.

(Contair	ner closure sy	ystem)				
Stability				2°C / 65% ± 5%RH ± 2°C / 75% ± 5%RH		
			Real time: 6 month Accelerated: 6 month			
Ž		Accelerated: 0, 3, 6 Real Time: 0, 3, 6				
Batch N	0.		T001	T002		
Batch Si	ize		5000 Tablets	5000 Tablets		
Manufac	cturing Date		08/2022	08/2022		
Date of	Initiation		08/2022	08/2022		
No. of E	Batches			03		
	DOCUME	NTS / DATA T	O BE PROVIDED	ALONG WITH STAI	BILITY STUDY DATA	A
1.	Reference	of previou		T	ot Submitted.	
		s with stability	study data of the	2.0		
2.	API manu	roval of API/ DML/GMP certificate of		5207/TS/2022 dated 14	submitted copy of GMP certificate No 22 dated 14-09-2022 issued by Drugs Contro on Government of Telangana valid till 14	
3.		for the procur om DRAP (in c	ement of API with ase 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.					
5.	•		HPLC software s on product testing		ot submitted.	
6.	and humidi (real time a	ty monitoring o nd accelerated)	ger for temperature f stability chambers		Submitted	
Sr. No.	Section	Observation			Reply by the firm	
1.	1.3.4	Valid copy of	DML of the applica	ant shall be submitted.		
2.	1.5.6	A •		of the drug substance		
2	2.2		shall be submitted.			_
3. 4.	2.3 3.2.S.4.1	•	cuted BMR's shall l			-
T.	5.2.5.7.1	product manu	s of the drug substance provided by the drug afacturer are different from that provided by stance manufacturer. Justification shall be			
5.	3.2.S.4.2	Analytical pro	ocedures of the drug substance submitted stance manufacturer are different from U Justification shall be submitted.			
6.	3.2.S.4.4	COA of the manufacturer while that	drug substance from drug substance has mentioned in-house specifications rom drug product manufacturer has P specifications. Clarification shall be			

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.	

Decisi	on: Registration Board deferred the case for	r 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 N 145/A, 145/AA & 147, Ramalingampally (V), Bomma ramaram (M), Yadadri — Bhuvanagiri (Dist)-508 12 Telangana, India. Firm has submitted copy of GMP certificate N 5207/TS/2022 dated 14-09-2022 issued by Drugs Contr Administration Government of Telangana valid till 1-12-2023.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templat Summarized information related to nomenclatur structure, general properties, solubility, physical formanufacturers, description of manufacturing process are controls, specifications, analytical procedures and it verification, batch analysis and justification especification, reference standard, container closure system and stability studies of drug substance and drup product is submitted.
Module III (Drug Substance)	Firm has submitted details of the drug substant including its nomenclature, structure, general properties solubility, physical form, manufacturers, description manufacturing process and controls, specification analytical procedures and its verification, batch analyst (B. No. OT-LID/12/20/048, Mfg. date 12-2020) and justification of specification, reference standar container closure system and stability studies of drug substance.
Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 60 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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, pharmaceutic development, manufacture, batch formula manufacturing process and process control, process validation protocols, control of drug product specifications, analytical procedures, verification analytical procedures, batch analysis, justification specifications, reference standard or materials, contains

			closure system and stability.	
	Dhamma aquti adl aquiyalana	and compositive	Pharmaceutical Equivalence is established against the	
	dissolution profile		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 validate product	tion/verification of	Method verification studio System suitability, specificing	es are submitted including ty, accuracy, precision.
		STABILITY	STUDY DATA	
Manufa	cturer of API		(V), Bommala ramaram (N	y No. 145/A, 145/AA & 147, M), Yadadri – Bhuvanagiri
API Lot	No.	OT-LID/12/20/048	3.	
	tion of Pack ner closure system)	Alu/Alu Blister 0f	2 x 7's tablets with leaflet.	
Stability	y Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Pe	eriod	Real time: 6 months Accelerated: 6 months		
Frequen	ncy	Accelerated: 0, 3, 6 Real Time: 0, 3, 6		
Batch N	lo.	T001	T002	
Batch S	ize	5000 Tablets	5000 Tablets	
Manufa	cturing Date	08/2022	08/2022	
Date of	Initiation	08/2022	08/2022	
No. of E	Batches		03	
	DOCUMENTS / DATA T	O BE PROVIDED	ALONG WITH STABILI	TY STUDY DATA
1.	Reference of previous approval of applications with stability study data of the firm (if any)		Not Su	bmitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		5207/TS/2022 dated 14-09-2	
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.		Subr	nitted

•		e Record of HPLC software udit trail reports on product testing	Not submitted.
5.	Record of I and humidi	Digital data logger for temperature ty monitoring of stability chambers nd accelerated)	Submitted
marl	ks of evaluat		
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-L (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, USFD approved. **Federal Register determination that product was no 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 Sura 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 an controls, specifications, analytical procedures and inverification, 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 substant including its nomenclature, structure, general properties solubility, physical form, manufacturers, description	

			manufacturing process and analytical procedures and its (B. No. 22ON000051, Mijustification of specification container closure system and substance.	verification, batch analysis fg. date 04 -2022) and ion, reference standard,	
	Stability studies (Condition Stability studies)	s & duration of	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 60 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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, contained closure system and stability. Pharmaceutical Equivalence is established against the innovator product i.e. Zofran 4mg Tablet, by Novartic 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).		
	Pharmaceutical equivalence dissolution profile	and comparative			
	Analytical method validation product	n/verification of	Method verification studies System suitability, specificity		
		STABILITY	STUDY DATA		
Manufa	cturer 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.	·		
	tion of Pack ner closure system)	Alu/Alu Blister	Alu/Alu Blister packing of 1 x 10's.		
Stability Storage Condition			Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Period			Real time: 6 months Accelerated: 6 months		
Frequen	ncy	Accelerated: 0, 3, Real Time: 0, 3,			
Batch N	Jo.	T1	T2		
Batch S	ize	5000 Tablets	5000 Tablets		
Manufa	cturing 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 applications firm (if any	of previous approval of s with stability study data of the)	Not Submitted.			
2.	* *		issu	y of GMP certificate No. 22063346 dated 30-05-2022 ed by Food and Drugs control Administration Gujrat e, 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		
Remark	s of evaluat	or:	•			
Sr. No.	Section	Observation		Reply by the firm		
1.	1.3.4	Valid copy of DML of the applica shall be submitted.	ınt	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 refere product with submission of full fe Ondansetron hydrochloride dihyd equivalent to 4 mg of ondansetron	e as rate	Firm has submitted revised label claim as follows; Each film coated tablet contains: Ondansetron Hydrochloride dihydrate eq. to Ondansetron		
3.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug production 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		
6.	3.2.P.2.2	zone Iva shall be submitted. 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 F2 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.	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	
7	2200	Justification shall be submitted for submission same results of CDP for both the strengths of ondansetron.	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. Compliance Record of URLC.	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. HPLC system used for the analysis of the trial was not 21 CFR compliant.	
	 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 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	E Each film coated tablet contains: Ondansetron HCl eq. to Ondansetron	

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 o Stability studies)	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 60 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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.	

	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/ver product	rification of	Method verification studie System suitability, specificit	\mathcal{E}	
	S	TABILITY	STUDY DATA		
Manufa	cturer of API	255, 256/P,	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.	22ON00005	51.		
	tion of Pack ner closure system)	Alu/Alu Bli	ster packing of 1 x 10's.		
Stability	Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Pe	eriod	Real time: 6 months Accelerated: 6 months			
Frequen	су	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch N	Jo.	T1	T2		
Batch S	ize	5000 Tablets	5000 Tablets		
Manufa	cturing Date	11/2022	11/2022		
Date of	Initiation	11/2022	11/2022		
No. of E	Batches		02		
	DOCUMENTS / DATA TO BE	PROVIDED	ALONG WITH STABILI	ΓΥ STUDY DATA	
1.	Reference of previous ap applications with stability study firm (if any)	proval of data of the	Not Sul	omitted.	
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.	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.	attested chromatogr	respective documents like ams, Raw data sheets, COA, ata sheets etc.	Submitted
5.	Compliance	e Record of HPLC software udit trail reports on product testing	Not Submitted
6.	Record of I and humidi	Digital data logger for temperature ty monitoring of stability chambers and accelerated)	Submitted
mark	s of evaluat	or:	
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 referent product with submission of full fee Ondansetron hydrochloride dihydra equivalent to 4 mg of ondansetron.	as follows; tee Each film coated tablet contains:
3.	3.2.S.4.3	Analytical method verificati studies of the drug substant performed by the drug produmanufacturer shall be submitted.	ce
4.	3.2.S.6	COA/details of the working standaused in the development of trbatches shall be submitted.	
5.	3.2.S.7	 Justification shall be submitted to over writing the real time stabil conditions in the submitted stabil data sheets for the drug substance. Real time stability data of the the batches for drug substance as properties. 	ity point. Firm has submitted new stability data sheets for the drug substance.
6.	3.2.P.2.2	 Justification shall be submitted to not performing CDP against to innovator brand. Details of the innovator product in Batch number, manufacturing day a expiry date etc. against white Pharmaceutical Equivalence performed shall be submitted we clear and visible pictorial evidence. 	he document wherein it is mentioned that CDP could be established with reference or comparator product. e. 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

		 Values of F₂ calculated for all the three mediums shall be submitted. Justification shall be submitted that how CDP is performed against the 	manufactured by M/s Pharmedic laboratories. Submitted.
		product with manufacturing date of 07-2018. • Justification shall be submitted for	Firm has submitted that it was typo mistake.
		submission same results of CDP for both the strengths of ondansetron.	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. 	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 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 atability atady. 	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
		applications with stability study data of the firm (if any) shall be submitted.	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)

GM	P 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.
Evic facil	lence of approval of manufacturing lity	Firm has submitted copy of letter No. F. 1-37/2003-Lic (Vol-I) dated 19/03/2021 specifying Sachet (General) section (New).
Stati	us of application	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)
Inter	nded use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☐ Domestic and Export sales
Dv	No. and date of submission	☑ Domestic and Export salesDy. No. 22776, dated 15/09/2023.
	nils of fee submitted	PKR 30,000/- vide slip No. 35439519573 dated: 12/09/2023.
The	proposed proprietary name / brand name	Qkast 4mg sachet.
	ngth / concentration of drug of Active rmaceutical ingredient (API) per unit	Each Sachet contains: Montelukast Sodium eq. to Montelukast 4mg
Phai	rmacotherapeutic Group of (API)	Leukotriene receptor antagonists. (R03DC)
Phar	rmaceutical form of applied drug	Oral Granules in Sachet.
Refe	erence to Finished product specifications	USP specification.
Prop	posed Pack size	As per SRO/DPC.
Prop	posed 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.
Nan	ne 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 10 th & 11 th march, 2021 valid till 11-05-2024.
Moc	dule-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.
Mod	lule 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 & Stability studies)	duration of	Stability study conditions: Real time: 30°C / 65% RH for Accelerated: 40°C / 75% RH f Batches: (MTN14-8015, MT) 0061)	for 06 months		
Module-III (Drug Product): Pharmaceutical equivalence and c dissolution profile			Firm has submitted details of its description, composite development, manufactur manufacturing process and validation protocols, contrappedifications, analytical pranalytical procedures, batch specifications, reference stand closure system and stability.	osition, pharmaceutical re, batch formula, process control, process rol of drug product, rocedures, validation of analysis, justification of		
		comparative	Pharmaceutical Equivalence innovator brand Singulair 41 quality tests Identification, Uniformity, Dissolution & Assiproduct and innovator product Comparative Dissolution is a same product i.e. Singulair 4m 1.2), Acetate buffer (pH 4.5) 6.8). Values of F ₂ are in accep	mg sachet by performing weight variation, Content say. Results of both the test are comparable. Iso performed against the g sachet in Acid media (pH & Phosphate Buffer (pH		
	Analytical method validation/ver product	rification of	Method verification studies are submitted including System suitability, specificity, accuracy, precision.			
	*	TABILITY	ABILITY STUDY DATA			
Manufac	turer of API	M/s Morepen Laboratories Limited, Village-Masulkhana, Parwanoo, Distt. Solan (H.P.) India.				
API Lot	No.	MK14-2550.				
	ion of Pack er 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 Per	riod	Real time: 6 Accelerated				
Frequenc	су		: 0, 3, 6 (Months) 0, 3, 6 (Months)			
Batch No	0.	T001	T002	T003		
Batch Si	ze	5000 Sachets	5000 Sachets	5000 Sachets		
Manufac	turing Date	07/2022	07/2022	07/2022		
Date of I	Date of Initiation		18/07/2022	19/07/2022		
No. of B	atches		03			
	DOCUMENTS / DATA TO BE	PROVIDED	ALONG WITH STABILITY	Y STUDY DATA		
	Reference of previous ap applications with stability study firm (if any)	proval of data of the	Submit	ted.		

2.	Approval o	of API/ DML/GMP certificate of	Cop	y of GMP certificate No. HFW-H (Drugs) 93/91	
	API manu	ifacturer issued by concerned	dated 05-01-2023 issued on the basis of inspection		
	regulatory a	authority of country of origin.	cond 2024	ducted on 10^{th} & 11^{th} march, 2021 valid till 11-05-4.	
3.	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.	attested chromatogr	bility batches will be supported by respective documents like rams, Raw data sheets, COA, ata sheets etc.		Submitted	
5.	Compliance	e Record of HPLC software udit trail reports on product testing		Not Submitted	
6.	and humidi	Digital data logger for temperature ty monitoring of stability chambers nd accelerated)		Submitted	
Remar	ks of evaluat	or:			
Sr. No.	Section	Observation		Reply by the firm	
1.	1.3.4	Valid copy of DML of the application shall be submitted.	cant	Firm has submitted copy of DML no. 000609 date of renewal w.e.f. 21-03-2022.	
2.	2.3	Table for literature references v correct information regarding drug substance with applicable shall be submitted.	the	Firm has submitted revised table for literature references. However, fee applicable for preregistration variation is not submitted.	
3.	3.2.S.4.1	Specifications of the drug substate from drug substance manufacturer different from the specification provided by the drug proceed manufacturer. Justification shall submitted.	are ions duct	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 submitted COA by the drug substate manufacturer are different from specifications submitted by distributions submitted substance manufacturer. Justificate shall be submitted.	the Irug	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	

-	 6. 	3.2.S.5 3.2.P.2.2	Details/COA of the reference standard/working standard used in the analysis of the development studies shall be submitted. 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.	manufacturer are different from the specifications submitted by drug substance manufacturer. The firm didn't answer the same. Firm has submitted USP Lot Number R10590 as reference standard. 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/preapproval 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

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
	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 10mg 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 Stability studies)	& duration of	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 24 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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 a dissolution profile	and comparative	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 product	n/verification of	Method verification studies are submitted including System suitability, specificity, accuracy, precision.
		STABILITY	STUDY DATA
	cturer of API	Banglore, Karar	
API Lot No. EBSN/2		EBSN/2210001	
(Container closure system)		Alu/PVC Bliste	r further packed in printed unit Carton.
			$\pm 2^{\circ}$ C / 65% ± 5 %RH $^{\circ}$ C $\pm 2^{\circ}$ C / 75% ± 5 %RH
Time Pe	riod	Real time: 6 mo Accelerated: 6 r	
Frequen	cy	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	

Batch No. T00		T001		T002	T003		
Batch Si	ize		1500 Tablets		1500 Tablets	1500 Tablets	
Manufa	cturing Date		08/2022		08/2022	08/2022	
Date of Initiation 12/08/2022		12/08/2022		13/08/2022	14/08/2022		
No. of Batches				03			
DOCUMENTS / DATA TO BE PROVID			BE PROVIDED	AL(NG WITH STABILI	TY 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.			dated cond Labo Distt	Copy of GMP certificate No. HFW-H (Drugs) 93/91 dated 05-01-2023 issued on the basis of inspection conducted on 10 th & 11 th march, 2021 for M/s Moreper Laboratories Limited, Village-Masulkhana, Parwanoo Distt. Solan (H.P.) India valid till 11-05-2024. <i>Not for the source of drug substance.</i>		
3.	Documents for the procurement of API with approval from DRAP (in case of import).						
4.	attested chromatog	bility batches will respective do rams, Raw data lata sheets etc.	cuments like	Submitted			
5.	•	e Record of I		Not Submitted			
6.	Record of and humidi	Digital data logger ity monitoring of st and accelerated)	for temperature	Submitted			
 Remark	ks of evalua			ı			
Sr. No.	Section	Observation			Reply by the firm		
1.	1.3.4	Valid copy of D shall be submitted	ML of the appliced.	cant	Firm has submitted 000609 date of renewa		
2.	1.5.6 Submitted GMP has mention Montelukast sodium, Desloratadi & Loratadine while the import drug substance is not mentioned the GMP. Clarification shall submitted.		line rted l in	Firm has submitted co HMF07-15031/147/20 by DCA Chuttugunta, 18-08-2022 with a val	py of certificate No. 22-AD-DCA issued Guntur (AP) dated		
3.	2.3 Table for literature references wi correct information regarding the drug substance with applicable for shall be submitted.		the	Firm has submitted literature references. However, fee app registration variation	licable for pre-		
4.	3.2.S.2.1	Fine Chem P	mentioned M/s R vt., Ltd, India the drug substa	as	Firm has submitted th of M/s Morepen Pha Firm has also sub	at mistakenly GMP arma was attached.	

		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 	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.
		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 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

		No. 14-1/2022-PEC dated 16-01-2023
	Valid copy of GMP certificate of	within 30 days.
	the drug substance manufacturer	Submitted.
	issued by concerned/relevant	Submitted.
	•	
	regulatory authority shall be submitted.	
•	Submitted chromatograms does not	
	reflect any time and wave length.	Firm has submitted that the
	Justification shall be submitted.	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.
•	Compliance Record of HPLC	The wavelength is mentioned in the
	software 21CFR & audit trail	standard analytical procedure of the
	reports on product testing shall be	product.
	submitted.	Firm has submitted that the
		chromatograms were obtained from
		"Waters" HPLC which is having the
•	Reference of previous approval of	software "Empower 2". The software is not
	applications with stability study	21CFR compliant.
	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. 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
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 10 th & 11 th 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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 24 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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.

	dissolution profile		Pharmaceutical Equivalence Kestine 20mg Tablet, B. No. by performing quality test variation, disintegration timunits, Dissolution & Assay, product and innovator product Comparative Dissolution is a same product i.e. Kestine 20m 1.2), Acetate buffer (pH 4.5 6.8). Values of F ₂ are in acceptable.	31369, Mfg. date 12-2021 sts Identification, weight the, Uniformity of dosage Results of both the test are comparable. The also performed against the ag Tablet in Acid media (pH of the Acid Media (p
	Analytical method validation product	n/verification of	Method verification studies System suitability, specificity	9
		STABILITY	STUDY DATA	
Manufa	acturer of API	M/s R.L. Fine C Banglore, Karar	hem (Pvt.) Ltd., No. 15, KBH nataka, India.	Industrial Area, Yelahanka,
API Lot	t No.	EBSN/2210001		
	otion of Pack ner closure system)	Alu/PVC Bliste	r further packed in printed unit	Carton.
Stability	y Storage Condition		$\pm 2^{\circ}$ C / 65% ± 5 % RH $^{\circ}$ C $\pm 2^{\circ}$ C / 75% ± 5 % RH	
Time Po	eriod	Real time: 6 mo Accelerated: 6 r		
Frequer	ncy	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch N	No.	T004	T005	T006
Batch S	Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufa	acturing Date	08/2022	08/2022	08/2022
Date of	Initiation	12/08/2022	13/08/2022	14/08/2022
No. of I	Batches		03	
	DOCUMENTS / DATA TO	BE PROVIDED	ALONG WITH STABILIT	Y STUDY DATA
1.	Reference of previous applications with stability st firm (if any)	approval of cudy data of the		mitted.
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Copy of GMP certificate N dated 05-01-2023 issued or conducted on 10 th & 11 th mar Laboratories Limited, Villag Distt. Solan (H.P.) India valid <i>Not for the source of drug su</i>	n the basis of inspection rch, 2021 for M/s Morepen ge-Masulkhana, Parwanoo, till 11-05-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Firm has submitted copy of No. E-1433986221657 date Ebastine BP 10 Kg, B. No. EB 2022 from M/s R.L. Fine Che Industrial area, Yelahanka, Bi Clearance certificate is for M/Firm has also submitted loa Laboratories wherein they have for product development.	Form clearance certificate d 03-06-2022 mentioning SN/2210001, Mfg. date 01-em Pvt., Ltd., No. 15, KBH ngalore, Karanataka, India. 's Epharm Laboratories. n letter from M/s Epharm

4.	attested chromatogr	respective documents like ams, Raw data sheets, COA, ata sheets etc.	Submitted
5.	-	e Record of HPLC software	Not Submitted
	21CFR & a	udit trail reports on product testing	
6.	and humidi	Digital data logger for temperature ty monitoring of stability chambers and accelerated)	Submitted
mark	s of evaluat	or:	
Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicar 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 mentione Montelukast sodium, Desloratadin & Loratadine while the imported dru substance is not mentioned in th GMP. Clarification shall b submitted.	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 wit correct information regarding th drug substance with applicable fe shall be submitted.	e 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. I Fine Chem Pvt., Ltd, India a manufacturer of the drug substance which is in contrast to 1.5.6 clarification shall be submitted.	of M/s Morepen Pharma was attached. Firm has also submitted new GMP
5.	3.2.S.4.1	Specifications of the drug substance from drug substance manufacture shall be submitted.	
6.	3.2.S.4.2	Analytical procedures of the dru substance from drug substance manufacturer shall be 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.	e 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. Deal time stability data of the three stability data of the three stability data of the three 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.
		Real time stability data of the thre batches for drug substance as per zone Iva shall be submitted.	or
9.	3.2.P.2.2	Details of the product i.e. name of manufacturer against which PE & CDP are performed shall be	ž

		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. 	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.	
		 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. 	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. 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.

	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			
	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.	
	i s s s s s s s s s s s s s s s s s s s		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 analysi (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 (Conditi Stability studies)	ons & duration of	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$: Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75$ Batches: (CITP/14002, CITF	$\% \pm 5\%$ RH for 06 months
	Module-III (Drug Product): Pharmaceutical equivalence and comparative dissolution profile		Firm has submitted details of its description, comp development, manufactur manufacturing process and validation protocols, conspecifications, analytical pranalytical procedures, batch specifications, reference stand closure system and stability.	osition, pharmaceutical re, batch formula, process control, process trol of drug product, rocedures, verification of a analysis, justification of
			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 valida product	tion/verification of	Method verification studies are submitted including System suitability, specificity, accuracy, precision.	
		STABILITY	STUDY DATA	
Manufac			ma Chem Limited, Unit-III Pl ty, Parawada, Visakhapatnar	
API Lot No				
Description of Pack (Container closure system) Alu/Alu Blist		Alu/Alu Blister fur	ther packed in bleach card uni	t Carton along with leaflet.
3 6			2°C / 65% ± 5%RH ± 2°C / 75% ± 5%RH	
Time Per	Time Period Real time: 6 month Accelerated: 6 month			
Frequenc	Frequency Accelerated: 0, 3, 6 Real Time: 0, 3, 6			
Batch No	0.	T001	T002	T003
Batch Si	ze	1500 Tablets	1500 Tablets	1500 Tablets
Manufac	cturing Date	10/2022	10/2022	10/2022

Date of 1	Date of Initiation 25/10/2022			26/10/2022	27/10/202	2	
No. of B	No. of Batches		<u> </u>	03			
DOCUMENTS / DATA TO BE PROVIDED) AL	ONG WITH STABILIT	Y STUDY DATA			
1.	application	Reference of previous approval of applications with stability study data of the firm (if any)			Submi	tted.	
2.	API mar		ed by concerned	Lim	y of GMP certificate ited is submitted instead m Limited.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).			O200 HCl 2020 Invo Lah Clea Lah Firm Phas	8/U3/E/20-21 dated 05-0 in-house 25 Kg, B. No. C 0 from M/s Vasudha phoice is attested by Assist ore dated 21-01-2021. arance certificate is for M	1-2021 mentioning ITP/2012008, Mfg arma chem limited ant Director, I&E //s Wimits Pharmac letter from M/s M/rein they have taken	g Itopride date 07-dd., India., DRAP, ceuticals,
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		r	Subm	_		
5.			HPLC software s on product testing		Submitted		
6.	and humid		ger for temperature f stability chambers				
Remark	s of evalua	ntor:		ı			
Sr. No.	Section	Observation			Reply by the firm		
1.	1.3.4	Valid copy of shall be submit	DML of the applicated.	cant	Firm has submitted co 000609 date of renew 2022.		
2.	1.5.6	Valid copy of GMP certificate of drug substance manufacturer shall submitted.			Firm has submitted co No. HMF07-14051/120 DCA issued by DC Guntur (AP) dated 13 validity of 03 years.	3/2021-ADMIN-CA Chuttugunta,	
3.	2.3.R	Executed copies of BMR's shall be submitted.		be	Submitted.		
4.	3.2.S.4. 3	 Justification shall be submitted regarding the Accuracy parameter the method verification studing wherein 80mg/ml of the analyted analyzed and 79mcg/ml amount recovered. Justification shall be submitted for not covering the concentration mentioned in the analytical method of the drug substance 0.2mg/ml in the submitted. 		er of dies e is t is for tion hod	Firm has submitted that analytical procedure the is 80mcg/ml and the am 79mcg/ml. 80mg/ml typographic error at 80mcg/ml 80mg/ml was Firm has submitted that of analysis for Itopride and validated for use method shows linearity in concordant with	amount analyzed ount recovered is was due to nd instead of written. in-house method e was developed at The validated results which are	

		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. 	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.	ı
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	Firm has submitted that the
	reflect any wave length. Justification	chromatograms were obtained from
	shall be submitted.	"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	Firm has submitted that the
	software 21CFR & audit trail reports	chromatograms were obtained from
	on product testing shall be submitted.	"Waters" HPLC which is having the
		software "Empower 2". The software is
		not 21CFR compliant.
	• Reference of previous approval of	r
	applications with stability study data	Firm has submitted that no previous
		approval is available.
	of the firm (if any) shall be	approvar is available.
	submitted.	

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
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 5 th 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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 03 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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.

	comparative dissolution profile		Brand i.e. Diampa 1 manufactured by M/s Gotests (Disintegration, As CDP is also performed Diampa 10mg tablets, by M/s Getz Pharma in Buffer (pH 4.5) & Phosthree mediums both	lence is established against the Omg tablets, B. No. 014FB5 etz Pharma by performing quality say, and Dissolution). against the same brand that is B. No. 014FB5 manufactured a Acid media (0.1N HCl), Acetate sphate Buffer (pH 6.8). In all the the applied formulation and the shown more than 85% release
	Analytical method v	validation/verification	Method validation studio Accuracy, precision, line	es have been submitted including: earity and specificity.
		STABILITY	STUDY DATA	
Manufactu	urer of API	No. 15, Donghai 5 th	rmaceutical Co., Ltd., Avenue, Zhejiang Provin Zone, Taizhou City, Zhe	ncial Chemical and Medical Raw ijiang Province, China.
API Lot N	lo.	432-020-19.		
Descriptio (Container	on of Pack r closure system)	Alu-Alu blister pack leaflet.	of 1 x 10's further pac	ked in a carton with insertion of
Stability S	torage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Perio	od	Real time: 06 months Accelerated: 06 months		
Frequency	1	Accelerated: 0,3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		EMP10-TR005	EMP10-TR006	EMP10-TR007
Batch Size	2	1000 Tablets	1000 Tablets	1000 Tablets
Manufactu	uring Date	04-2021	04-2021	09-2021
Date of In	itiation	19-05-2021	19-05-2021	21-10-2021
No. of Bat	tches		03	
	REQUE	ST OF EXEMPTION	FROM ON SITE INSE	PECTION
The firm h			estigation of their submitt e checklist approved by t	ed stability data and provided the he Registration Board.
		Administ	rative Portion	
1.	1. Reference of previous approval of applications with stability study data of the firm (if any)		No	t submitted.
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			te No. ZJ20190132 dated 21-11- 24 is submitted by the firm.
3.	Documents for the procurement of API with approval from DRAP (in case of import).		1038548487861 dated 2 Empagliflozin B. No. 13 2022.	y of clearance certificate No. E-29-04-2022 mentioning 1.5 kg of 3900-211202, mfg. date of 02-01-data sheets have mentioned batch 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.	•	Record of HPLC software udit trail reports on product		Submitted
6.		Digital data logger for and humidity monitoring of hambers (real time and		Submitted
e <u>marks</u>	OF Evaluato			
Sr. No.	Section No.	Observation		Response by the firm
1.	1.3.4	 Valid copy of DML of the shall be submitted as the prism w.e.f. 07-04-2010. Valid copy of GMP cerinspection report conducted three years shall be submitted. 	ertificate/last d within last ed.	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. Evidence of approval of mar facility/section approval from 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		Firm has submitted revised specifications for the drug substance wherein they have changed limits of

the drug product manufacturer has

mentioned NMT 0.5%, clarification shall

analytical method provided by the drug

275nm, column temperature 40 °C,

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,

composition (60:40) and mobile phase of

Verification of analytical procedures

the

• Provide results of analysis of relevant

batch(es) of Drug Substance performed

substance manufacturer i.e. λ

volume

volume

and

Clarification shall be submitted.

by

manufacturer shall be submitted.

conditions

 80μ l,

10µl,

distilled

drug

be submitted.

injection

injection

acetonitrile

performed

Chromatographic

3.2.S.4.2

3.2.S.4.3

3.2.S.4.4

4.

5.

6.

residue on ignition from NMT 0.5% to

Fee required for change in specification

Firm has submitted revised analytical

method for drug substance as per

parameters of the drug substance

No clarification is submitted.

NMT 0.1%.

max

diluent

diluent

water.

product

is not submitted.

manufacturer.

Submitted.

Submitted.

		has Donne Don for a constant of	
		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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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. 	Firm has submitted that CDP is performed against the brand leader.
		• Justification shall be submitted for performing only three tests in pharmaceutical equivalence studies.	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.	Firm has submitted that content uniformity test is not a stability parameter.
		 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. 	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.
		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 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.
		• Reference of previous approval of applications with stability study data of the firm (if any) shall be 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	M/s Pharmedic Laboratories (Pvt.) Ltd., 16-km,
	Authorization Holder	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
	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 5 th 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,
Module III (Drug Sul			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.
		ostance)	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 (Dru	g substance.)	Stability study conditions and batches: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 03 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 03 months Batches: (13900-211201, 13900-211202 & 13900-211203)
	Module-III (Drug Product): Pharmaceutical equivalence and comparative dissolution profile		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 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 of product		ralidation/verification	Method validation studies have been submitted including: Accuracy, precision, linearity and specificity.
		STABILITY	STUDY DATA
Manufactu	No. 15, D		rmaceutical Co., Ltd., Avenue, Zhejiang Provincial Chemical and Medical Raw i Zone, Taizhou City, Zhejiang Province, China.
API Lot No.		432-020-19.	
Description of Pack (Container closure system) Alu-Alu blister plants leaflet.		leaflet.	x of 1 x 10's further packed in a carton with insertion of
Stability S	torage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$	
Time Period Real time: 12 months		Real time: 12 months	S

	Accelerated: 06 mon	Accelerated: 06 months		
Frequency		Accelerated: 0,3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	EMP25-TR005	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	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.

	Administr	rative Portion
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.		Copy of GMP certificate No. ZJ20190132 dated 21-11-2019 valid till 20-11-2024 is submitted by the firm.
3.		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.	
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)	Submitted

Remarks OF Evaluator:

 Chains of Evaluator.				
Sr.	Section	Observation	Response by the firm	
No.	No.			
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.	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.	
		Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	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. 	Firm has submitted new COA of the drug substance wherein they have mentioned Zhejiang Tianyu Pharma as manufacturer.
7.	7. 3.2.S.7.3 Complete real time and accele stability studies for the three batch the drug substance shall be submitte		Firm has submitted new stability data sheets for the drug substance. Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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. 	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.
		• Reference of previous approval of applications with stability study data of the firm (if any) shall be 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	
	☐ 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
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.)		rug substance.)	Stability study conditions and batches: Metformin HCl. Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 60 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months Batches: (MET099/13, MET100/13 & MET101/13) Empagliflozin: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months Batches: (180205, 180227 & 180325)
	comparative dissolution profile		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 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).
			Method validation studies have been submitted including: system suitability, accuracy, and precision.
STABII		STABILIT	TY STUDY DATA
Abhilasha I Gujrat state GMP Certif Control Adı Empagliflo Kaifeng Pha		Gujrat state India. GMP Certificate N Control Administra Empagliflozin: Kaifeng Pharmace	chloride. Pvt. Limited 1408, 1409, GID, EST. Anklishwar, 393002, fo: 19081546 valid up to 25/08/2022 issued by Food & Drugs ation of Gujarat State, India. utical (Group) Company Limited. China nan Street, Kaifeng, Henan Province, China.
API Lot No. MET065/19 (Metf		MET065/19 (Metform HF180721 (Empage	ormin HCl)
Description of Pack			ck 7's, 10's, 14's, 20's, 28's & 30's.
Stability Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}$			2°C / 65% ± 5%RH ± 2°C / 75% ± 5%RH
Time Period	Time Period Real time: 06 mont Accelerated: 06 mo		
Frequency Accelerated: 0,3, 6		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
Manufactui	ring Date	04-2020	04-2020	04-2020
Date of Init	iation	24-04-2020	27-04-2020	28-04-2020
No. of Batc	ehes		03	
	REQUES	T OF EXEMPTION	ON FROM ON SITE INS	PECTION
			nvestigation of their submit the checklist approved by	tted stability data and provided the the Registration Board.
		Admini	strative Portion	
1.	applications with stability study data of the firm (if any)		Xetine 10mg tablets whi and was presented in 29th held on 09th April, 2020. Registration Board dec	ch was conducted on 03-03-2020 4 th meeting of Registration Board ided to approve registration of and Xetine Tablets 20mg with
certificate of API manufacturer issued		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		
3.	Documents for the procurement of API with approval from DRAP (in case of		till 31-12-2025. Empagliflozin: Firm has submitted copy	of clearance certificate No. 2326
	import).		attested by Assistant Director I&E, DRAP, Isla Metformin HCl: Firm has submitted Exp dated 05-06-2019 mention MET065/19 with quantit Director I & E, DRAP, Isla Director I & E, DRAP, Isla Metformin HCl:	ort Invoice No. Exp013/2019-20 ioning Metformin HCl, B. No. y of 300kg attested by Assistant lamabad dated 01-07-19.
4.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		S	Submitted
5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing			Submitted	

	T			
6.	temperature and humidity monitoring			Submitted
	•	chambers (real time and		
	accelerated)			
e <u>marks</u>	OF Evaluato	r:		
Sr.	Section	Observation		Response by the firm
No.	No.			
1.	1.2	Table content from module 1 5 shall be submitted.	to module	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.
•	proposed she the registrati Manufacture	elf life and on accelerated stu on application.	dies for six m	s on long term stability studies throughonouths as per the commitment submitted est three batches as per the commitme
52.			M/s Asian (Continental (Pvt.) Ltd., Continental Hous Sultan Road, KDA Scheme-1, Karachi.
			_	Continental (Pvt.) Ltd., D/32, S.I.T.E. Sup
			Copy of GN 09-03-2021	MP certificate No. 07/2021-DRAP (K) dat issued on the basis of inspection conducted Sebruary, 2021 is submitted

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
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, manufacturing process and analytical procedures and its (B. No. S7137, Mfg. date 26-specification, reference standard stability studies of drug s	d controls, specifications, verification, batch analysis 01-2021) and justification of ard, container closure system
Stability studies (Drug subs		stance)	Firm has submitted stability drug substance at both accelerated substance at both accelerated substance $40^{\circ} \pm 2^{\circ}$ C $/75\% \pm 5\%$ RH stability data is conducted at 3 for 60 months. (Batch No. E5)	lerated as well as real time stability data is conducted at for 6 months. The real time $30^{\circ}\text{C} \pm 2^{\circ}\text{ C} / 75\% \pm 5\% \text{ RH}$
	Module-III (Drug Product): Pharmaceutical equivalence and comparative dissolution profile		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.	
			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	
Manufactu	rer of API	M/s. Proto Chemicals AG, (Grunenthal GmbH Quality Control) Tschachen 2, CH-8756 Mitloedi (Glarus-Sued) Switzerland.		
API Lot N	0.	S7137.		
Description (Container	n of Pack closure system)	Clear, colorless to yellowish solution filled in glass ampoules 1ml USP type I.		
Stability Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Perio	od	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- No. of Batches		04-11-2021	02-09-2021	04-11-2021
			03	
	Administrative Portion			
1.	Reference of previous applications with stability s firm (if any)	approval of tudy data of the	N ₂	A

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.		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)	

Remarks of Evaluator:

Remarks of Evaluator:								
	Sr.	Section	Observations	Firm's Response				
	No.	Number						
	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
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 06 months Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ 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,

			specifications, analytical analytical procedures, ba	cols, control of drug product, I procedures, validation of atch analysis, justification of tandard or materials, container ty.
	Pharmaceutical E Comparative Dissolution	on Profile	product against the innova suspension 50mg/ml, B. N by Tasman Pharma by appearance, identification the test product and refe specifications limit and co	are not a per BP monograph
	Analytical method vali product		Firm has submitted analy reports for drug product.	rtical method validation study
		STABILITY S	TUDY DATA	
Manufactu	urer of API	0 0		d., g Industrial Area, Shouguang
API Lot N	Vo.	RM-6127.		
Descriptio (Container	on of Pack r closure system)	Yellow colour suspension filled in Amber PET Bottle packed with syringe dropper and leaf insert.		
Stability S	Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Perio	od	Real time: 6 months Accelerated: 6 months	S	
Frequency	<i>y</i>	Accelerated: 0, 3, 6 (M) Real Time: 0, 3, 6 (M)	*	
Batch No.		21SB(B)-067-01	21SB(B)-068-02	21SB(B)-069-03
Batch Size	e	2250 ml	2250 ml	2250 ml
Manufactu	uring Date	08-2021	08-2021	08-2021
Date of In	itiation	20-09-2021	20-09-2021	20-09-2021
No. of Bat	tches		03	
			ALONG WITH STABII	
stal	ference of previous approbility study data of the fi	rm (if any)		N/A.
ma	oproval of API/ DML/C unufacturer issued by thority of country of orig	concerned regulator	y 03-2019 issued by	te No. SD20190888 dated 13-Shandong Food and Drug Il 12-03-2024 is submitted.
	3. Documents for the procurement of approval from DRAP (in case of imposition).		21VIT-439 dated 22-0 Clozapine USP, B. No	06-2021 specifying 25 Kg of to. A-51012102002, mfg. date toice is cleared by Assistant
atte	ta of stability batches ested respective docume w data sheets, COA, sun	nts like chromatogram	J	ubmitted.
5. Co	impliance Record of HF dit trail reports on produc	PLC software 21CFR	& S	ubmitted.

6.	Record of Digital data logger for temperature and		Submitted.	
	time and ac	monitoring of stability chambers (real		
		, , , , , , , , , , , , , , , , , , ,		
	rks of Evalu	Observation	Dealer has the Come	
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.	specifications are USP specifications, while	
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.	from drug substance and drug product manufacturer is same as per USP method.	
3.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.		
4.	3.2.S.5	Details/COA of the working standard used in the development studies shall be 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. 	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.	
6.	3.2.P.5.1	Justification shall be submitted for not following the BP specifications for applied formulation for pH and assay test.	1	

		pH limit in BP is 4.0 to 6.0 while the specification submitted are 6.5 to 7.0.	specifications as per BP. They also submitted revised assay limits/specifications.
		Assay limits in BP are 95.0% to 105.0% while the specification submitted are 90.0%	Fee for revision of specifications shall be submitted.
		to 110%.	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

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
	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 $40^{\circ} \pm 2^{\circ}$ C $/75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at 30° C $\pm 2^{\circ}$ C $/65\% \pm 5\%$ 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.	
comparative dissolution profile			Firm has performed pharmaceutic the product Toradol injection 30m date 11, 2020 by performing qual Identification, pH, Assay, particular Bacterial endotoxin).	ng, B. No. C5290, Mfg. lity tests (Description,
	Analytical method validatio product	n/verification of	Method verification studies have linearity, range, accuracy, precision	•
	1*	STABILITY	STUDY DATA	7 1
Manufac	turer 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.		
	ion of Pack er closure system)	Clear, colorless type I.	to yellowish solution filled in gla	ss ampoules 1ml USP
Stability	Storage Condition		$\pm 2^{\circ}$ C / 65% $\pm 5\%$ RH $^{\circ}$ C $\pm 2^{\circ}$ C / 75% $\pm 5\%$ RH	
Time Per	riod	Real time: 6 months Accelerated: 6 months		
Frequenc	cy	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No).	EXP-I-183	PLT-I-013	PLT-I-014
Batch Siz	ze	1000 ml	1500 ml	1500 ml
Manufac	turing Date	12-2021	12-2021	12-2021
Date of I	nitiation	12-2021	01-2022	01-2022
No. of Ba	atches		03	
	T		ative Portion	
1.	Reference of previous applications with stability s firm (if any)	approval of tudy data of the	NA	
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			av Chemicals Limited, arwala Road, Mohali by Food & Drugs ed by the firm.
3. Documents for the procurement of API wit 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.		

	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)	

	emarks of Evaluator:				
Sr.	Section	Observations	Firm's Response		
No.	Number				
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 Barrett 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.

	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	
	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) Minutes of 335th meeting of Registration	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 p	product is submitted.	
	Stability studies (Drug substance.) Module-III (Drug Product): Pharmaceutical equivalence and comparative dissolution profile		properties, solubility, description of manufactures specifications, analytical batch analyses (185008 justification of specification	of nomenclature, structure, general physical form, manufacturers, cturing process and controls, procedures and its verification, 003, mfg. date 06-2018) and on, reference standard, container ty studies of drug substance.	
				5% ± 5% RH for 36 months 75% ± 5% RH for 06 months	
			description, composition manufacturers, descriptio controls, process valid analytical procedure and it and justification of sp	of the drug product including its a, pharmaceutical development, n of manufacturing process and dation protocol, specifications, is validation studies, batch analysis recification, reference standard, n and stability studies of drug	
			i.e. Voltral Emulgel 29	ce is established against the Brand %, GSK OTC (Pvt.) Ltd., by (Disintegration, Identification, y).	
	Analytical method validation/verification of product		Method validation studies have been submitted including: Accuracy, precision, linearity and specificity.		
		STABILIT	TY STUDY DATA		
Manufactur	rer 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 (Container	of Pack closure system)	Printed and sealed Alu-Alu tubes having plastic cap further packed in board unit carton.			
Stability St	orage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Period		Real time: 09 months Accelerated: 06 months			
*		Accelerated: 0,3, 6 Real Time: 0, 3, 6,			
Batch No.		19	20		
Batch Size		500 Tubes	500 Tubes		
Manufacturing Date 09-2021		09-2021	09-2021		
Date of Init	Date of Initiation 11-09-2021		11-09-2021		
No. of Batc	hes		02		
	REQUE	EST OF EXEMPTION	ON FROM ON SITE INSI	PECTION	
			nvestigation of their submit the checklist approved by	ted stability data and provided the the Registration Board.	

1.		of previous approval of with stability study data of any)	Not submitted.		
2.		of API/ DML/GMP of API manufacturer issued ed regulatory authority of origin.	Not submitted.		
3.		for the procurement of API ral from DRAP (in case of	Not submitted.		
4.	supported documents	tability batches will be by attested respective like chromatograms, Raw COA, summary data sheets	e v		
5.	_	Record of HPLC software udit trail reports on product		Not Submitted	
6.	temperature of stability	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 shall be submitted as the is w.e.f. 25-12-2015.	provided one	Firm has once again submitted the same DML w.e.f. 25-12-2015. Valid DML is required.	

Sr.	Section	Observation	Response by the firm
No. 1.	No. 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 	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-
		inspection report conducted within last three years shall be submitted.	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

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 Fumarate25mg
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months. Batch No. (2018082801, 2018082901 & 2018083001)

	Pharmaceutical Equivalence and Comparative Dissolution Profile		its d man proc spec anal spec	lescription, composition aufacture, manufacturin cess validation protococifications, analytical sytical procedures, ba	of the drug product including a pharmaceutical development, g process and process control, ols, control of drug product, procedures, validation of tch analysis, justification of andard or materials, container of
			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 va of product	lidation/verification	Not	Submitted.	
		STABILITY	STU	UDY DATA	
Manufactur	er of API				
API Lot No).	19090401.			
Description (Container	of Pack closure system)	Alu Alu blister of 3 x 10's further packed in bleech card unit carton along with leaflet.			
Stability St	orage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Perio	d	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.
Manufactur	ring Date	10-2019		10-2019	10-2019
Date of Init	iation	10-12-2019		10-12-2019	10-12-2019
No. of Bato	ehes			03	
DO	OCUMENTS / DATA	TO BE PROVIDE	D AI	LONG WITH STABII	LITY STUDY DATA
1.	Reference of previous approval applications with stability study data of firm (if any)			Not	t submitted.
2.	Approval of API/ DML/GMP certificate API manufacturer issued by conceregulatory authority of country of origin.				
3.			with	Not	t submitted.
4.	Data of stability batches will be supported attested respective documents chromatograms, Raw data sheets, Co summary data sheets etc.		like	S	ubmitted.
5.	Compliance Record of HPLC software 21C & audit trail reports on product testing			Not	t submitted.

6.		d of Digital data logger for temperature	Not submitted.
	and humidity monitoring of stability chambers		
	,	ime and accelerated)	
	ks of Evalu	<u> </u>	D 1 1 4 6
Sr. No.	Section	Observation	Reply by the firm.
	1.3.4	Valid copy of DML and GMP	
•	1.5.4	certificate/last inspection report	
		conducted within last three years of the	
		applicant shall be submitted.	
	1.3.5	Evidence of approval of manufacturing	
		facility/section approval from licensing	
		division shall be submitted.	
	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.	
	1.5.15 to	Signed undertakings shall be submitted.	
	1.5.20	8	
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.	
	3.2.S.4.1	Specification of the drug substance from	
•	0.2.51.11	drug substance manufacturer shall be	
		submitted.	
	3.2.S.4.2	Analytical procedures of the drug	
		substance from both the drug substance	
		and drug product manufacturer shall be	
	22542	submitted.	
•	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.	
	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	

• 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		
11.	3.2.3.7	Real time stability data of three batches	
		for the drug substance from drug	
		substance manufacturer as per zone Iva	
10		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 accelerated) shall be submitted.	and	
Decisio	on: Registration Board deferred the case for s	ubmission 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 248 th 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 Bromide0.5mg Salbutamol Sulfate 3mg eq. to Salbutamol2.5mg	
	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:

			Batches: (H1000062, H11	0020 & H130073)
	Module-III Drug Prod	duct:	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 Comparative Dissolu		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 analyteports for drug product.	tical method verification study
		STABILITY	STUDY DATA	
Manufacturer of API		Salbutamol Sulfate:	lli, 126852 Casaletto Lodig Plot Nos. A-2, A-33 & A	iano (Frazione Mariano), Italy37/2/2, M.I.D.C., Patalganga,
API L	ot No.	1750000358, HDP16	0180, 9800/0316.	
	iption of Pack ainer closure system)	Inhalational solution packed in LDPE respules further wrapped in a foil and packed in unit cartons with leaflet.		
Stabili	ity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time 1	Period	Real time: 24 months Accelerated: 6 months		
Freque	ency	Accelerated: 0, 3, 6, 8 Real Time: 0, 3, 6 (M	9, 12, 18, 24 (Months) Ionths)	
Batch	No.	18J003	18J004	18J005
Batch	Size	180L	180L	180L
Manut	facturing Date	08-2018	08-2018	08-2018
Date of	of Initiation	05-09-2018	08-09-2018	24-09-2018
No. of	Batches		03	
	DOCUMENTS / DATA	A TO BE PROVIDED	ALONG WITH STABII	LITY STUDY DATA
1.	Reference of previous app stability study data of the		ith Su	ıbmitted.
2.	Approval of API/ DML/GMP certificate of A manufacturer issued by concerned regulate authority of country of origin.		Olon S.p.A, Via Livell (Frazione Mariano), Ita Copy of GMP certifica by AIFA, Italy on the b 29-06-2018 valid for the Salbutamol Sulfate:	i, 126852 Casaletto Lodigiano aly. te No. IT-API/4/H/2021 issued asis of inspection conducted on

3.	Documents for the procurement of API with approval from DRAP (in case of import).			D.C., Patalganga, Raigad 410220 Maharashtra p., India. Yof GMP certificate No. NEW-WHO-D/CERT/KD/107920/2022/11/39128 dated 17-022 issued by Food and Drug Administration Bandra-Kurla Complex, Bandra(E), Mumbai till 16-02-2025 is submitted. **Tropium Bromide:** That submitted copy of invoice No. 7000000306 if 03-03-2017 mentioning 0,500 kg of Ipratropium inde, B. No. 9800/03/16. The invoice is cleared assistant Director, DRAP, Karachi dated 07-04-17. **Utamol Sulfate:** Yof commercial invoice No. CIP/EXP/006 dated 9-2016 mentioning 1200 gm of salbutamol hate attested by Assistant Director, DRAP, chi dated 05-10-2016 is submitted by the firm. That also submitted copy of Form 6 attested by stant Director, DRAP, Karachi dated 05-10-2016.
4.	attested res			Submitted.
5.	•	nce Record of HPLC software 21CFR & I reports on product testing		Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) Submitted.			
Rema	rks of Evalu	iator:		
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 Salbutamol2.5mg
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	shall be submitted. 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 acceler stability of both the drug substances 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. 	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
		• 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.	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 Salbutamol2.5mg

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. 27734 dated 20-09-2022 PKR 150,000/-: vide slip no. 7062718500 dated 23-09-2022. Paracetamol Injection 1g/100ml Each 100ml solution contains1g Injection Analgesic and Antipyretic In-house 1 bottle of 100ml packed in printed unit box with a product leaflet As per SRO USFDA Approved (Acetaminophen 1g/100ml) Parazyl L Injection of M/s. Searle IV solution Pvt. Ltd., Lahore (Reg.no. 078617) 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 procedures and its validation, batch procedures and its validation, batch
Paracetamol Injection 1g/100ml Each 100ml solution contains1g Injection Analgesic and Antipyretic In-house 1 bottle of 100ml packed in printed unit box with a product leaflet As per SRO USFDA Approved (Acetaminophen 1g/100ml) Parazyl L Injection of M/s. Searle IV solution Pvt. Ltd., Lahore (Reg.no. 078617) 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
Each 100ml solution contains1g Injection Analgesic and Antipyretic In-house 1 bottle of 100ml packed in printed unit box with a product leaflet As per SRO USFDA Approved (Acetaminophen 1g/100ml) Parazyl L Injection of M/s. Searle IV solution Pvt. Ltd., Lahore (Reg.no. 078617) 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
Injection Analgesic and Antipyretic In-house 1 bottle of 100ml packed in printed unit box with a product leaflet As per SRO USFDA Approved (Acetaminophen 1g/100ml) Parazyl L Injection of M/s. Searle IV solution Pvt. Ltd., Lahore (Reg.no. 078617) 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
Analgesic and Antipyretic In-house 1 bottle of 100ml packed in printed unit box with a product leaflet As per SRO USFDA Approved (Acetaminophen 1g/100ml) Parazyl L Injection of M/s. Searle IV solution Pvt. Ltd., Lahore (Reg.no. 078617) 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
In-house 1 bottle of 100ml packed in printed unit box with a product leaflet As per SRO USFDA Approved (Acetaminophen 1g/100ml) Parazyl L Injection of M/s. Searle IV solution Pvt. Ltd., Lahore (Reg.no. 078617) 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
1 bottle of 100ml packed in printed unit box with a product leaflet As per SRO USFDA Approved (Acetaminophen 1g/100ml) Parazyl L Injection of M/s. Searle IV solution Pvt. Ltd., Lahore (Reg.no. 078617) 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
leaflet As per SRO USFDA Approved (Acetaminophen 1g/100ml) Parazyl L Injection of M/s. Searle IV solution Pvt. Ltd., Lahore (Reg.no. 078617) 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
USFDA Approved (Acetaminophen 1g/100ml) Parazyl L Injection of M/s. Searle IV solution Pvt. Ltd., Lahore (Reg.no. 078617) 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
Parazyl L Injection of M/s. Searle IV solution Pvt. Ltd., Lahore (Reg.no. 078617) 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
(Reg.no. 078617) 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
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.
M/s. Anqiu Lu'an Pharmaceuticals Co. Ltd. No.35 Weixu North Road, Aniqu, Shandog, China
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.
Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $75\% + 5$ RH. The stability study data is till 36 months.
Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container

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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability study data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH. The real time stability study data of 3 batches is for 36 months

Evaluation by PEC:

	ion by The.	
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.

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259.	Name, address of Applicant / Importer	M/s. Zhangjiakou Dongfang Pharmaceutical Pakistan Pvt. Ltd. D-2,2 nd 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-2,2 nd 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-2,2 nd 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
Status of annihilation	☐ 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	☐ Finished Pharmaceutical product import
the these	☐ 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: Latanoprost0.125mg
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 $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$ and the real time stability study is conducted at $-20 \pm 5^{\circ}\text{C}$. 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 $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \pm 5\%$ RH for 6 months. The real time stability study data is conducted at $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$. The real time stability study data of 3 batches is for 36 months
Ev aluat	ion by PEC:	
S.no.	Section Observa	tions/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	
2.	1.5.4	09/10/2022.	
3.	3.2.S.4.1-	Provide specification and analytical procedure of drug substance used for	
	3.2.S.4.2	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.

O. Name, add	dress of Applicant / Importer	M/s. Martin Dow Limited Plot no.37 Sec: 19 K.I.A. Karachi 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		
Details of	Drug Sale License of importer			
	nd address of marketing ion holder (abroad)	M/s. ANFARM HELLAS S.A. Administration Office: 4 ACHAIAS STR & TRIZINIAS, Kifissia Attiki,14564, Greece. Manufacturing Site: 61 st Km, NAT. RD. ATHENS-LAMIA,Schimatari Viotias,32009,Greece		
Name, add	dress of manufacturer(s)	Name of Manufacturer: M/s. ANFARM HELLAS S.A. Manufacturing Site: 61 st Km, NAT. RD. ATHENS-LAMIA,Schimatari Viotias,32009,Greece.		
Name of 6	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 agency ag	f letter of authorization / sole reement	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 Sugammadex100mg
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 324 th 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}/75 \pm 5\%$ RH and the real time stability study is conducted at $25^{\circ}\text{C} \pm 2^{\circ}\text{C}/60 \pm 5\%$ 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. 8018704,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% \pm 5% RH for 6 months. The real time stability study data is conducted at 30°C ± 2 °C / 75% \pm 5% RH. The real time stability study data of 3 batches is for 24 months			
Evaluat	ion by PEC:				
S.no.	Observations/Deficiencies/ Short- comings	Response of the Firm			
1.	Submit valid, original and legalized Fr Sale certificate issued by releva regulatory authority of country of original since the submitted CoPP stated that it applied product is not freely available the exporting country.	nt 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 Manufacturer Abroad since the submitte GMP certificate was expired in 2022.	Firm submitted a copy of valid GMP certificate of Manufacturer Abroad.			

3.	Submitted sole agency agreement and	Firm replied that per ml of injection strength is
	CoPP reflects that the drug product is	mentioned in the sole agency agreement and
	imported in 1ml pack size, while the	CoPP while the applied pack size is 1's in
	product part of module-3 reveals that the	presentation of 2ml ampoule.
	drug product is manufactured in 2ml pack	
	size, clarify the disparity regarding the	
	volume of injection along with supporting	
	legalized document.	
4.	Submit complete stability data of three	Submitted.
	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.	

Decisio	cision: 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 1 st Floor, Karachi		
	Details of Drug Sale License of importer	License No: 143 Address: 19-SR-7 Combell street Azzainab Court 1 st Floor, Karachi Address of Godown: 1. S.No. 14G/Floor Karinji & others Plot WO7/15 Napier 2. 2D,2 nd 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		
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}/75\pm$ 5% RH and the real time stability study is conducted at $25^{\circ}\text{C} \pm 2^{\circ}\text{C}/60 \pm 5\%$ RH. The stability study data is till	

			48 months.	
	Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
			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 validation/ve	method erification of product	Firm has submitted analytical method validation studies for the applied product.	
	Container cl product	losure system of the drug	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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / 75% \pm 5% RH for 6 months. The real time stability study data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / 75% \pm 5% RH. The real time stability study data of 3 batches is for 36 months	
Evaluat	ion by PEC:			
S.no.	Section		ons/Deficiencies/ Short-comings	
2.	1.3.3 3.2.S.4.1	 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. 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 293 rd 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

2.]	Name, address of Applicant / Importer	M/s. Calory Pharma 75-B, Circular street No.13 Central Lane Phase-II DHA Karachi. 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	
	Details of Drug Sale License of importer		
	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	
	\square 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}/75 \pm 5\%$ RH and the real time stability study is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}/65 \pm 5\%$ 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 $\pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability study data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH. The real time stability study data of 3 batches is for 36 months.		

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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
	2.2.39	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 07 th October,2021.
	Evidence of approval of manufacturing facility	Firm submitted GMP certificate no.46/2021-DRAP(K) dated 07 th 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: Baclofen5mg
	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 A manufacturer.		Organics Limited B6-B tate Indore (M.P), India	37,Sector-C,Sanwer	
	Module-II (Quality Over Summary)	has summarized in general properties, description of manu analytical procedur justification of sp	QOS as per WHO QOS- formation related to nome solubilities, physical for affacturing process and cont res and its verification, le pecification, reference so stability studies of drug so	enclature, structure, rm, manufacturers, rols, specifications, batch analysis and tandard, container	
	Module-III Drug Substance:	nomenclature, structure, structure, manufacturer controls, specification batch analysis and structure.	ed detailed drug substance eture, general properties, so es, description of manufactions, analytical procedures d justification of special closure system and stabil	olubilities, physical eturing process and and its verification, fication, reference	
	Stability Studies of Drug Substan (Conditions & duration of Stabilistudies)	substance at both a accelerated stability RH for 6 months. T	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 18 months.		
	Module-III Drug Product:	composition, pha manufacturing pro- protocols, control specifications, and procedures, batch	data of drug product includarmaceutical developments and process control, of excipients, control sytical procedures, verificanalysis, justification or materials, container of	ent, manufacture, process validation of drug product, ation of analytical of specifications,	
	Pharmaceutical Equivalence a Comparative Dissolution Profile	reference product l	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 meth validation/verification of product		for drug substance as well as drug product.		
	S	TABILITY STUDY DA	BILITY STUDY DATA		
Manufact	curer of API		M/s. Panchsheel Organics Limited B6-B7,Sector-C,Sanwer Road, ndustrial Estate Indore (M.P), India		
API Lot No. BO		BCF/2122007	3CF/2122007		
•		Clear, colorless solution bottle 30ml	Clear, colorless solution with raspberry flavour filled in amber glass oottle 30ml		
			Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
		Real time: 6 months Accelerated: 6 months			
Frequenc	у	Accelerated: 0, 3, 6 (Macelerated: 0, 3, 6 (The state of the s		
Batch No	١,	21SB(B)-167-01	21SB(B)-168-02	21SB(B)-169-03	
Batch Siz	re	75 BOTTLES	75 BOTTLES	75 BOTTLES	
Manufact	turing Date	10-2021	10-2021	10-2021	
			1	1	

No. of I	Batches	03	
DOCUMENTS / DATA TO BE PROVIDED ALONG			G 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).		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.		
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.	_	Firm replied that reference product is available
	approved in reference regulatory agencies	only in 300ml pack size. However for patient
	in the volume size of 60ml,100ml &200ml.	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 1 st , 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	•	procedure of drug product specifically assay method in
accorda	ance with BP monograph of "Baclofen	Oral Solution" and submit the performance report in
accorda	ance with revised analytical method at ne	ext 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 07 th October,2021.
	Evidence of approval of manufacturing facility	Firm submitted GMP certificate no.46/2021-DRAP(K) dated 07 th 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: Baclofen10mg
	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,

		manufac controls, verificat reference	e, general properties, soluturers, description of man specifications, analytication, batch analysis and justice e standard, container closured for drug substance and drug	nufacturing process and all procedures and its ification of specification, are system and stability
Module-III Drug Substance:		nomencl physical process and its specifica	s submitted detailed drug sature, structure, general form, manufacturers, descand controls, specification verification, batch analystion, reference standard, cility studies of drug substar	properties, solubilities, ription of manufacturing as, analytical procedures sis and justification of container closure system
Stability Studies of Drug Subs (Conditions & duration of studies)		substance The acce 75% ± 5	s submitted stability study of e at both accelerated as well elerated stability data is co low RH for 6 months. The red at 30°C ± 2°C / 65% ± 5	Il as real time conditions. Inducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / real time stability data is
Module-III Drug Product:	Module-III Drug Product:		s submitted data of drug on, composition, pharm ture, manufacturing proce validation protocols, contro product, specifications, ion of analytical proce tion of specifications, s, container closure system	aceutical development, ess and process control, l of excipients, control of analytical procedures, dures, batch analysis, reference standard or
	Pharmaceutical Equivalence and Comparative Dissolution Profile		s submitted pharmaceutical e product Baclofen oral of M/s. Thames R0004)	
Analytical method validation/ of product		reports f	or drug substance as well a	9
N. C	STABILI			
Manufacturer of API		M/s. Panchsheel Organics Limited B6-B7,Sector-C,Sanwer Road, Industrial Estate Indore (M.P), India		
API Lot No.	BCF/21220	007		
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 Real Time:			·	
Batch No. 21SI		170-01	21SB(B)-171-02	21SB(B)-172-03
Batch Size 7		TLES	75 BOTTLES	75 BOTTLES
Manufacturing Date	10-2021		10-2021	10-2021
No. of Batches			03	•
DOCUMENTS / DATA TO	DED ALC	NG WITH STABILITY S	TUDY DATA	

1.	Reference of previous approval applications with stability study data o firm (if any)	of N/A f the
2.	Approval of API/ DML/GMP certifica API manufacturer issued by conce regulatory authority of country of origin	
3.	Documents for the procurement of API approval from DRAP (in case of import)	
4.	Data of stability batches will be supported attested respective documents chromatograms, Raw data sheets, Commany data sheets etc.	like testing.
5.	Compliance Record of HPLC soft 21CFR & audit trail reports on product te	
6.	and humidity monitoring of stal 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.
l -	ss 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	However COA of sorbitol from raw material			
	dated 1 st , December,2023.	manufacturer did include the impurity testing			
		related to the presence of ethylene glycol and			
7.	Ctores andition annified by the	diethylene glycol.			
/.	Storage condition specified by the reference product and BP monograph of	Firm replied that mistakenly it is written as store below 30°C the actual correct storage is store			
	"Baclofen Oral Solution) is "Baclofen oral	below 25°C. Revised SOP is submitted.			
	solution should be stored below 25°C,	below 25 C. Revised 501 is submitted.			
	while the storage condition mentioned by				
	you is store below 30°C, Justify the storage				
	condition recommended by you for your				
	applied product.				
8.	Justify for not adopting the BP	Firm replied they have performed the stability			
	specifications for the drug product when	studies as per BP method but they skipped to			
	the monograph of Baclofen Oral Solution	mention BP specification therefore they have			
	is present in BP.	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	Firm submitted the in-use stability data of 28 days.	1		
	guidance document approved by	Stability study has been performed on 30ml pack			
	Registration Board which specifies that	size, which is not included in the demanded pack			
	"Summary of additional stability studies (if	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".		<u> </u>		
Decision	Decision: Deferred for revision of analytical procedure of drug product specifically assay method in				

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.

	3	1 8
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: Olanzapine10mg
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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 60 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ 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 Equivalenc Comparative Dissolution Profile	and Cor comparate	mparative disso	maceutical equivolution profile epra 10mg Tab	against the	
	Analytical method validation/v of product		•	tical method verifies as well as drug p	•	
	ST	ΓΑΒΙLΙΤΥ	STUDY I	DATA		
Manufa	cturer of API	Plot N PARAWA	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/004	0420			
	tion of Pack ner closure system)	Alu-Alu b	olister pack	ed in unit carton	(1×10's)	
Stability	Storage Condition			$C / 65\% \pm 5\% RF$ $2^{\circ}C / 75\% \pm 5\%$		
Time Pe	eriod		: 6 months ed: 6 montl	hs		
Frequen	cy		ed: 0, 3, 6 (e: 0, 3, 6 (N			
Batch N	o.	TZA001		TZA002		TZA003
Batch Si	ize	2500 tab		2500 tab		2500 tab
Manufa	cturing Date	01-2021		01-2021		01-2021
No. of E	Batches	3				-
	DOCUMENTS / DATA TO BE I	PROVIDE	D ALONG	WITH STABIL	ITY STUDY DA	TA
1.	Reference of previous approval of applications with stability study data of the firm (if any)			The firm has no	t submitted any d	ocument.
2.	Approval of API/ DML/GMP certificate of manufacturer issued by concerned regulatory auth of country of origin.				/B/CC/R issued b	y FDCA
3.	Documents for the procurement of API with app from DRAP (in case of import).			Copy of letter CD(I&E) date wherein the per APIs including test/analysis and	er No.8623/2020	is submitted port different ne purpose of is granted.
4.	Data of stability batches will be supported by a respective documents like chromatograms, Rasheets, COA, summary data sheets etc.				Submitted	
5.	Compliance Record of HPLC software 21CFR trail reports on product testing			Submitted		
6.	Record of Digital data logger for temperat humidity monitoring of stability chambers (rand accelerated)				Submitted	
	Remarks of Evaluator:					
S.no.				Response of the	ne Firm	
1.	Provide raw data sheets and chromatograms of analytical method verification report monograph.			-	_	-

_				
		verification report as the submitted report		
		did not specify the assay procedures.		
	2.	Comparative dissolution profile report of	Firm submitted the revised CDP report in which	
		drug product revealed that at 30 minutes	more than 80% drug release within 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.		
$\ \ $	3.	Adapt the acceptance limit of dissolution	Revised specification submitted by the firm.	
		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.		
	4.	Provide details that which lot number of	API lot no. LAN/0040420 has been used in	
		drug substance has been used in	manufacturing of each batch of drug product.	
		manufacturing of each batch of drug	GMP certificate of API manufacturer	
		product. Also provide documents	M/s.RAMPEX Labs Pvt. Ltd., India has been	
		confirming evidence of import of each lot	submitted by the firm which was valid till 20-04-	
		of drug substance used in manufacturing	2021, however the manufacturing license of	
		of these batches of drug product.	manufacturer is valid till 29-09-2024 as written on	
		• Submit valid Good Manufacturing	the said GMP certificate.	
		Practice (GMP) certificate of the Drug		
		Substance manufacturer issued by		
		relevant regulatory authority of		
		country of origin.		

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			
	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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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				n has submitted analytical orts for drug substance as v		
		STABILITY S	TUD	Y DATA		
ı v e			rmaceutical Co., Ltd. AX			
API Lot	No.	3619102201				
	tion of Pack ner closure system)	Tablets are packet	ed in	the PVC/aluminum foil bli	ister packs.	
Stability	Storage Condition	Real time: 30°C = Accelerated: 40°C		/ 65% ± 5%RH °C / 75% ± 5%RH		
Time Pe	riod	Real time: 6 mon Accelerated: 6 m		3		
Frequen	су	Accelerated: 0, 3 Real Time: 0, 3,				
Batch N	0.	T01		T02	T03	
Batch Si	ize	5000 Tablets		5000 Tablets	5000 Tablets	
Manufac	cturing Date	03-2021		03-2021	03-2021	
No. of B	Batches		•	03		
267.	Name, address of Applicant Authorization Holder	/ Marketing	M/s Jawa Pharmaceuticals Private Limited 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore, Punjab, Pakistan			
	Name, address of Manufacto	uring 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 0 07-2020 based on inspection conducted on 04-03-202		
	Evidence of approval of ma facility	nufacturing	Firm has submitted copy of letter of grant of section dated 25-06-2019 specifying Tablet Psychotropi Section.			
	Status of application		☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)			
	Dy. No. and date of submiss	sion	Dy.No 25348 dated 07-09-2022			
	Details of fee submitted		Rs.30,000/- dated 18-07-2022			
	The proposed proprietary na	ame / 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 prod		act specifications	USP			
	Proposed Pack size		As per SRO			
	Proposed unit price		As per SRO			
	The status in reference regu	latory authorities	Lexapro Tablet by Custom Pharmaceuticals Limited, U.K ,NDA 21-323			

For generic drugs (me-too st	ratus)	Es-Pramcit Tablet by Nabi Qasim Pharmaceuticals (Pvt), Ltd (Reg.No. 061661)	
Name and address of API m	anufacturer.	Zhejiang Haisen Pharmaceutical Co., Ltd. AXiangtan Village, Liushi Street, Dongyang City, Zhejiang Province 322104, China	
Module-II (Quality Overall S	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. 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	
Stability Studies of Drug Su (Conditions & duration of St			
Module-III Drug Product:		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
Pharmaceutical Equiv Comparative Dissolution Pro		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 STABILITY STABIL		Firm has submitted analytical method validation study reports for drug substance as well as drug product.	
		TUDY DATA	
Manufacturer of API		Pharmaceutical Co., Ltd. AXiangtan Village, Liushi City, Zhejiang Province 322104, China.	
API Lot No.	3619102201		
Description of Pack (Container closure system)	Tablets are packe	ed in the PVC/aluminium foil blister packs.	
Stability Storage Condition		= 2°C / 65% ± 5%RH C ± 2°C / 75% ± 5%RH	
Time Period Real time: 6 mo Accelerated: 6 m			

Frequency		Accelerated: 0, 3, 6 (Real Time: 0, 3, 6,9,		·		
Batch No.			T01	T02	T03	
Batch Siz	ze		5000 Tablets	5000 Tablets	5000 Tablets	
Manufac	turing Date	:	02-2021	02-2021	02-2021	
No. of B	atches			03		
	DOCUME	ENTS / DATA TO	BE PROVIDED ALO	ONG WITH STABILITY	STUDY DATA	
1.		e of previous apprestudy data of the fi	oval of applications w irm (if any)	ith N/A		
2.	manufact		GMP certificate of A concerned regulated in.	ory Zhejiang Haisen Ph	narmaceutical Co., Ltd Liushi Street, Dongyan de 322104, China.	
3.		nts for the proc from DRAP (in ca			Firm has submitted copy of ADC Permission by AD (I&E) DRAP, Lahore.13.01.2020	
4.	attested r	espective docume	will be supported nts like chromatogram nmary data sheets etc.		alytical record for produc	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing			& N/A		
6.	humidity		ger for temperature a stability chambers (re	Firm has submitted recall for temperature and hu time and accelerated st	midity monitoring of rea	
Remarks	of Evaluate	or:				
Section # Observations 1.6.5 Submit valid DM drug substance n		ML/GMP certificate manufacturer, issued lory authority of count	drug substance.			
analytical proced certificate for manufacturer.			is specifications, analytice Batch analysis certifications substance manufactures.	Firm submitted drug substance specifications, analytical procedure and Batch analysis certificate form drug substance manufacturer.		
3.2.P.8.3 Submit following • Analytic product including			es			

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 06 th June,2022.
Evidence of approval of manufacturing facility	Firm submitted grant of additional section letter (new section) dated 25 th 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.

			I			
	Module-III Drug Product:		substance a accelerated RH for 6 m	submitted stability study data at both accelerated as well as a stability data is conducted at months. The real time stability $6\% \pm 5\%$ RH for 36 months.	real time conditions. The $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$	
			Firm has submitted data of drug product including 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 Equivaler Comparative Dissolution Pro		innovator	submitted pharmaceutical e product Keppra 100mg etam 100mg / mL) manufacture K.	/ mL Oral Solution	
	Analytical validation/verification of pro-			ubmitted analytical method veri ance as well as drug product.	fication study reports for	
			Ŭ	JDY DATA		
Manufa	acturer of API	Manufact	uring site an	arer: Shangyu Jingxin Pharmaceutical Co., Ltd. uring site and address: No. 31 Weisan Road, Hangzhou Bay Shangyu and Technological Development Area, Zhejiang Province, China.		
API Lo	t No.					
				slucent clear oral solution fill and sealing packed in specific		
Stability	y Storage Condition			C / 65% ± 5%RH CC / 75% ± 5%RH		
Time Po	eriod		: 6 months ed: 6 months	s		
Frequer	ncy		ed: 0, 3, 6 (Ne: 0, 3, 6 (M			
Batch N	Vo.		P-OSLP- 2001	RD-GP-OSLP- 22002	RD-GP-OSLP- 22003	
Batch S	Size	20 t	oottles	20 bottles	20 bottles	
Manufa	cturing Date	03-1	0-2022	03-10-2022	03-10-2022	
No. of 1				03		
DOCUMENTS / DATA TO BE PROVIDED			OVIDED AI	LONG WITH STABILITY ST	UDY DATA	
1.	Reference of previous approval of application with stability study data of the firm (if any)		ny) pr	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 297 th 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.		gulatory (Z	irm has submitted copy of ZJ20190095) issued dated 05-0 8-2024.		
3.	Documents for the procure approval from DRAP (in case			irm submitted the copy of DRA the procurement of API.	P attested invoice related	
	l			^		

	D	
4.		by Firm has submitted analytical record for product testing. like
	chromatograms, Raw data sheets, Co summary data sheets etc.	OA,
5.	Compliance Record of HPLC software 21CF	R & Submitted
	audit trail reports on product testing	
6.		and Firm has submitted record of digital data logger for
		real temperature and humidity monitoring of real time and
	time and accelerated)	accelerated stability chambers.
	s of Evaluator:	
S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Formulation contain preservative, so	Firm submitted preservative efficacy test report.
	preservative effectiveness studies to be	
	performed as per recommendations of	
2.	pharmacopoeia and shall be submit. Submit the analysis report/COA of	Firm submitted the COA of propylene glycol and
۷.	excipients propylene glycol and glycerine	glycerine includes the results of impurity testing related
	which includes the results of impurity	to the presence of ethylene glycol and diethylene glycol.
	testing related to the presence of ethylene	prosente or emplone gryoti and diethylene gryoti.
	glycol and diethylene glycol, in	
	compliance of notification issued by DRAP	
	vide letter No. F.3-42/2023-QC dated 1st	
	December, 2023.	
3.	Justify for keeping the pH acceptance	Firm submitted the reply that "Lepsi Oral Solution was
	criteria different from that recommended	developed against attached reference of "Levetiracetam
	by the USP monograph of "Levetiracetam oral solution".	Oral Solution" from the USP 43, 2020. Later the pH
	oral solution.	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	monograph Firm replied that they included the test of specified
7.	specified microorganism in the	microorganism in the specification of drug product.
	specification of drug product, since the test	interoorganism in the specification of drug product.
	is recommended by the USP monograph of	
	"Levetiracetam oral solution".	
5.	Justify the batch size against the number of	Applicant has used R&D equipment for syrup
	units to complete stability studies.	manufacturing. One 100mL pack/bottle was used for
6.	According to the additional section letter	testing at each time point during the stability studies and
	issued by the Licensing Division, syrup	the batch size is sufficient for performing stability
	section (general) granted on 25-10-2023,	testing for at least 24 months.
	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	
<u> </u>	2022, arong with minimum nanding	

	capacity of the equipment used in the formulation of trail batches.	he
•	"batch release data at initial time point" enough to perform complete stability stulife along with commitment to perform c Manufacturer will place first three produproposed shelf life and on accelerated sturegistration application.	issued upon submission of "batch manufacturing record" and of newly manufactured trial batches with batch size sufficient idies as per prescribed quality standards, till the claimed shelf complete stability studies on newly manufactured trial batches uction batches on long term stability studies throughout udies for six months as per the commitment submitted in the lation of first three batches as per the commitment submitted
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 06 th June,2022.
	Evidence of approval of manufacturing facility	Firm submitted grant of additional section letter (new section) dated 25 th 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.

NA

For generic drugs (me-too status)

	Module-II (Quality Overall Summary) H S S S S S S S S S S S S S S S S S S			S PVT. LIMITED Address of : CTX Lifesciences Pvt. Ltd. Block No. llla Road GIDC, Sachin, Surat – 394 230	
			has summarized inform general properties, solu description of man specifications, analytica analysis and justification	S as per WHO QOS-PD template. Firm ation related to nomenclature, structure, abilities, physical form, manufacturers, sufacturing process and controls, all procedures and its verification, batch on of specification, reference standard, in and stability studies of drug substance	
	Module-III Drug Substance:		nomenclature, structure, form, manufacturers, de controls, specification verification, batch and	etailed drug substance data related to general properties, solubilities, physical escription of manufacturing process and as, analytical procedures and its lysis and justification of specification, ainer closure system and stability studies	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product:		Firm has submitted stability study data of 3 batches of drug		
	Pharmaceutical Equivaler Comparative Dissolution Prof		Firm has submitted pharmaceutical equivalence against the innovator product Lyrica Oral Solution 20 mg/ml of Pfizer, Inc.		
	Analytical method validation/of product	verification	Firm has submitted analytical method verification study reports for drug substance as well as drug product.		
		STABI	LITY STUDY DATA		
Manufac	cturer of API	CTX Lifes	SCIENCES PVT. LIMITED Address of Manufacturing Facility: ciences Pvt. Ltd. Block No. 251-252 Sachin- Magdalla Roadnin, Surat – 394 230 Gujarat, INDIA.		
API Lot	No.	22PL00005	52.		
Description of Pack (Container closure system) HDPE bottl		le with a white cap.			
, ,		$30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ 1: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Pe	riod	Real time: 6 Accelerated			
Frequen	cy		l: 0, 3, 6 (Months) 0, 3, 6 (Months)		
Batch N	О.		GN-L001.	GN-L002	
Batch Si	ize		2000 bottles	2000 bottles	

Manufa	cturing Date	01/20		03-10-2022	
No. of I	No. of Batches		03		
	DOCUMENTS / DATA T	O BE PROVIDED .	ALONG WITH S	STABILITY STUDY DATA	
1.	with stability study data of the firm (if any)		product "Dexsto	red to onsite inspection report of om 30mg and 60mg capsule", which 21-09-2020 & 22-09-2020 and 7th meeting of Registration Board heliuary 2021.	was was
2.	Approval of API/ DML/GMF manufacturer issued by con authority of country of origin.		Firm has not sul manufacturer.	bmitted copy of GMP Certificate of	API
3.	Documents for the procurer approval from DRAP (in case		Firm submitted attested from DI	the copy of commercial invoice with RAP.	thout
4.		locuments like	Firm has submit	ted analytical record for product test	ting.
5.	Compliance Record of HPLC audit trail reports on product to		Submitted		
6.	Record of Digital data logger in humidity monitoring of stabilitime and accelerated)			itted record of digital data logger I humidity monitoring of real time ility chambers.	
Remark	s of Evaluator:				
S.no.	Observations/Deficiencies	/ Short-comings	F	Response of the Firn	
1.	Submit analytical method ve drug substance performed by manufacturer.		Firm submitted	d analytical method verification substance performed by the drug	
2.	Formulation contain preservative effectiveness performed as per reco	rvative effectiveness studies to be rmed as per recommendations of			
3.	pharmacopoeia and shall be submit. 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.		120mL that is a packaging mater volume does not GenLin Oral So	at "Our claimed filled volume is as per requirement in Pakistan and rial available in market. The filled that affect the stability and efficacy of polution. And 120mL also enhance mpliance, convenience and cost	
4.	Provide reference/rational volume of applied product.	of claimed filled			
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		the BP specificat	t "Finished Product complies with ions, more over in case of finished BP reference standard was used for Product".	
6.	According to the innovator stability of innovator drug performed at the ICH a conditions of 30°C ± 2°C humidity, ± 5%), justify for stability of applied drug alternative storage condition	or review report product has been lternative storage (at 35% relative not performing the product at the	conditions for temperature of room temperatumention of temperaturentions.	hat "The Recommended storage the reference product specify a 30°C, which aligns with typical ure. However, there is no specific humidity control within these therefore, we have followed orage 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 +/- 20 C/35% Relative Humidity (RH) +/-5% and a 45 day use period for opened bottles when stored at or below 30o C +/- 20 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	lication ☐ New Drug Product (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)	(M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi,
Module-III Drug Product:	Firm has submitted data of drug product including 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 and Comparativ Profile	e Dissolution p	Firm has submitted pharmaceutical equivalence against the compar product Ticovate Nasal Spray (Each spray contains Fluticas Propionate 50mcg) of M/s. Saffron Pharmaceuticals Pakistan (Ltd.		contains Fluticasone	
Analytical validation/verification			ed analytical method verificat well as drug product.	tion study reports for	
	STA	ABILITY STUDY	ZDATA		
		M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA			
API Lot No.	F	FTP/922001			
Description of Pack (Container closure system)			y suspension, filled in a plast ing pump packed in unit carto		
Stability Storage Condition			2°C / 65% ± 5%RH ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 mont Accelerated: 6 mo			
Frequency		Accelerated: 0, 3, Real Time: 0, 3, 6			
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 / I	DATA TO BE PR	ROVIDED ALON	IG WITH STABILITY STUD	Y DATA	
1. Reference of previous with stability studies.			•		
2. Approval of API/manufacturer issuauthority of count	ued by concerned	retificate of API Firm has not submitted copy of GMP Certificate of AF manufacturer (M/s. Sawati Spentose Pvt. Ltd A-1/211 Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA).			
3. Documents for to approval from DF	_		m submitted the copy of commested from DRAP.	nercial invoice without	
I	ective docume Raw data she	ents like tes	m has submitted analytical rec ting.	ord for product	
5. Compliance Reco			t Submitted		
6. Record of Digita and humidity mo (real time and acc	nitoring of stabili	ity chambers ten	m has submitted record of d apperature and humidity monitor delerated stability chambers.		
Remarks of Evaluator:					
S.no. Observations/Defici 1. Section 1.6.5(a) spector Pharmaceuticals, Plandustrial Estate, Sar India is the drug so while the GMP ce	cify that M/s. Shot No 9,10,11 ntej, Ta: Kalol, Gubstance manufactificate of M/s.	nankus Firm has Milan ujarat, cturer, . Flax	Response of the Firm not submitted the reply of this		
Laboratories (Pvt.) Li been submitted in se					

	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	Firm has not submitted the specification and analytical procedure of drug substance by drug product
	substance by drug product manufacturer.	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,	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.
	justification is required in this regard.	
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	Firm has not submitted the reply of this query.
0.	•	Titti has not subfinited the reply of this query.
	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.	
7.	Justify for not adopting the analytical	Firm replied that "As per general Monograph of BP,
/ .		
	procedure of drug product in accordance with	change in mobile phase allowed and our Mobile phase
	the BP monograph of fluticasone propionate	is within the limit"
	nasal spray as evident from the submitted	However, the firm has submitted only the statement
	procedure in the relevant section.	without any calculations with reference to the allowable
	procedure in the relevant section.	I
		adjustment limit of mobile phase.
8.	Please specify the details of spray	Firm replied that 120 Spray = 14ml+0.2ml.
	configuration/no. of actuation with reference	
	to the filled volume.	
9.	Justify for not performing the stability of	Firm has not submitted the reply of this query.
	drug product at alternate condition	
	recommended in ICH guidelines for drug	
	product packaged in plastic containers.	
10	Justify for not including all the quality test	Firm has not submitted the reply of this query.
	recommended by the BP monograph of	
	fluticasone propionate nasal spray while	
	performing the stability of drug product.	
11	Submit documents for the procurement of	Firm has submitted procurement document of API
	API including copy of commercial invoice	without attested by AD (I&E) DRAP
	U 1.	without attosted by AD (ICL) DIVAL
	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.	
12	Provide Batch Manufacturing Record (BMR)	Submitted.
	of all stability batches.	

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.

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 pr specifications	oduct	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: Stability Studies of Drug Substance (Conditions & duration of Stabilistudies)		nce:	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.		
			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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / 75% \pm 5% RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / 65% \pm 5% RH for 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.		
	ST		ABILITY STUDY DATA		
Manufac	cturer of API	M/s. Sawati 195, INDIA	Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396		
API Lot	No.	FTP/922001			
_	ion of Pack ner closure system)		r hazy suspension, filled in a plastic bottle fitted with a meter dose ump packed in unit carton along with leaflet.		
Stability	Storage Condition	Real time: 3	$0^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$		

		Accelerated: 40	$0^{\circ}C \pm 2^{\circ}C / 75^{\circ}$	% ± 5% RH			
Time Po	eriod	Real time: 6 months Accelerated: 6 months					
			Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)				
Batch N	No.	T-00	02	T-003	T-004		
Batch S	Size	83 Bo	ttles	83 Bottles	83 Bottles		
Manufa	acturing Date	11/20	022	11/2022	11/2022		
No. of l	Batches			03			
	DOCUMENTS / DA	TA TO BE PRO	VIDED ALO	NG WITH STABILITY S	TUDY DATA		
1.	Reference of previou applications with stabili the firm (if any)		NA				
2.	Approval of API/ DML/ of API manufacture concerned regulatory country of origin.		manufacturer	ot submitted copy of (M/s. Sawati Spentose Pvi, Gujarat - 396 195, IND	t. Ltd A-1/2111, Phase		
3.	Documents for the proc with approval from DR import).			ed the copy of commerci	al invoice without atte	sted	
4.	supported by attest documents like chrom	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets		nitted analytical record fo	r product testing.		
5.		ance Record of HPLC software & audit trail reports on product		d			
6.			and humidity				
Remark	s of Evaluator:						
S.no.	Observations/Deficience comings			Response of the Fin	rm		
1.	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.		, , , , , , , , , , , , , , , , , , ,	ot submitted the reply of t			
2.	procedure used for an substance by drug produ	alysis of drug act manufacturer	g procedure manufactur		by drug product		
3.	Justify for performi studies on assay metho the assay procedure reco	d different from	However the specification	ed that "Method is as be drug substance manufact on for drug substance as in the relevant section.	cturer complied USP		

	USP monograph of Mometasone Furoate.	
4.	Justify for not including the test of optical	Firm submitted the revised quality analysis report of drug
4.		substance in which test of optical rotation is included.
	rotation while quality analysis of drug	substance in which test of optical folation is included.
	substance by drug product manufacturer.	
5.	Submit the amended label claim	Firm replied "Each spray = 0.1ml Mometasone Furoate=
	specifying the delivered volume	50mcg".
	containing the quantity of mometasone	However, the label claim of innovator product is "Each
	Furoate	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	Firm has not submitted the reply of this query.
	preservative effectiveness studies to be	
	performed as per recommendations of	
	pharmacopoeia and shall be submit.	
7.	Submit the analysis report/COA of	Firm has not submitted the reply of this query.
,.	excipients glycerine which includes the	Thin has not suchinated the reply of this query.
	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.	
8.	Justify for not performing all the quality	Firm has not submitted the reply of this query.
	test in accordance with BP monograph of	
	Mometasone Furoate aqueous nasal	
	spray while establishing the	
	pharmaceutical equivalence against the	
	comparator product.	
9.	Provide the reference of label claim	Firm has not submitted the reply of this query.
	mentioned in the pharmaceutical	
	equivalence table	
10	Justify for not including the test of	Firm has not submitted the reply of this query.
	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.	
11		Firm has not submitted the reply of this query.
11	procedure of drug product in accordance	1 IIII has not suchineed the topiy of this query.
	with the BP monograph of Mometasone	
	Furoate aqueous nasal spray as evident	
	from the submitted procedure in the	
10	relevant section.	
12	Please specify the details of spray	
	configuration/no. of actuation with	
10	reference to the filled volume.	
13	Justify for not performing the stability of	Firm has not submitted the reply of this query.
	drug product at alternate condition	
	recommended in ICH guidelines for drug	
	product packaged in plastic containers.	

test recommer of Mometason	t including all the quality aded by the BP monograph ne Furoate aqueous nasal erforming the stability of	
of API included invoice attestory attestory and a substantial drug substantial drug substantial product. Also confirming evicts of drug substantial drug substa	ments for the procurement ding copy of commercial ed by AD (I&E) DRAP. Is that which lot number of the has been used in the good provide documents and the documents of the december of the december of each lot the need in manufacturing the good drug product.	
	h Manufacturing Record stability batches.	Submitted BMR reflects that 14ml filled in each bottle Label claim Each spray contains: Mometasone Furoate50mcg (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:

	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		
Dy. No. and date of submission	☐ Domestic and Export sales 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		
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.		

(Conditions & duration of Stability studies) Module-III Drug Product:		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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} /75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} /65\% \pm 5\%$ RH for 36 months. 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} /75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} /65\% \pm 5\%$ RH for 36 months.			
		Firm has submitted data of drug product including 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 validation/verification of pr		Firm has submitted analytical method verification study reports for drug substance as well as drug product.			
	STA	BILITY STU	DY DATA		
M/s. AART M.I.D.C. Ta Sitagliptin I Fluoride In		Hydrochloride: II DRUGS LTD MANUFACTURING FACILITY Plot No. G– 60, arapur, Tal Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA. Phosphate Monohydrate: dustrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning 23000, China			
API Lot No.	L-D05-CP1	1422001 ME	F/12031196		
Description of Pack (Container closure system)		lor oblong shape, film coated tablet, Score on one side in Alu-Alu ss in unit carton with leaflet			
		30°C ± 2°C / 65% ± 5%RH d: 40°C ± 2°C / 75% ± 5%RH			
Time Period	Real time: 6 Accelerated				
1 7		d: 0, 3, 6 (Months) 0, 3, 6 (Months)			
Batch No. TTI		R040	TTR041	TTR042	
Batch Size 600 t		ablets	600 tablets	600 tablets	
Manufacturing Date 04/2		2023.	04/2023.	04/2023.	
No. of Batches			03		
DOCUMENTS / DAT	A TO BE PR	OVIDED AL	ONG WITH STABILITY STUD	Y DATA	
1. Reference of previous approval of applications with stability study data of the firm (if any)					

2.	API manufa	API/ DML/GMP certificate of acturer issued by concerned	Firm has manufact	submitted copy of GMP Certificate of both API urers.	
3.	regulatory authority of country of origin. 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.		
	approval from	n DRAP (in case of import).	attested I	rom DRAP.	
4.	attested re	espective documents like ms, Raw data sheets, COA,		submitted analytical record for product testing.	
5.		Record of HPLC software dit trail reports on product testing			
6.	and humid		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Remark	s of Evaluato	r:	l		
S.no.	Section	Observations/Deficiencies/ S comings	Short-	Reply	
1.	3.2.S.4.1- 3.2.S.4.2	_	•	Firm submitted the specification and analytical procedure of both drug substance.	
2.	3.2.S.4.1	0 0 1	e) for the when the sitagliptin	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 ve report of both drug substance p by the drug product manufacture	erformed	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 l substance by drug product manu	both drug	Submitted	
5.	3.2.S.7	Stability data of sitagliptin p specified that the drug s complied USP specification v other sections of drug substa- claimed that the in-house sitagliptin phosphate has been us manufacturing of drug product.	substance while the ance part complied	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 dissolution test in term of Q value, sin the BP monograph of applied produce recommends the acceptance limit 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 sar procedure as recommended by monograph of Metformin and S Tablets, since the submitted n different from the procedure official monograph of BP.	the BP itagliptin nethod is given in	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 accordance with BP Monograp		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 Hydrochloride500mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin50m
Pharmacotherapeutic Group of (API)	For the treatment of Diabetes mellitus Type II/Hypoglycen 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) I of Reg.no. 055443.
Name and address of API manufacturer.	Metformin Hydrochloride: M/s. AARTI DRUGS LTD MANUFACTURING FACILITY P No. G– 60, M.I.D.C. Tarapur, Tal Palghar, Dist.: Thane - 401 50 Maharashtra. INDIA. Sitagliptin Phosphate Monohydrate Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin Ci Liaoning Province -123000, China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, gene properties, solubilities, physical form, manufacturers, description manufacturing process and controls, specifications, analytic procedures and its verification, batch analysis and justification specification, reference standard, container closure system a stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubilities, physic form, manufacturers, description of manufacturing process a controls, specifications, analytical procedures and its verification batch analysis and justification of specification, reference standar 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 dr substance (sitagliptin phosphate) at both accelerated as well as r time conditions. The accelerated stability data is conducted at $40 \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months. Firm has submitted stability study data of 3 batches of dr substance (Metformin Hydrochloride) at both accelerated as well real time conditions. The accelerated stability data is conducted $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stabil data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description composition, pharmaceutical development, manufacturing process and process control, process validating protocols, control of excipients, control of drug produst specifications, analytical procedures, verification of analytic procedures, batch analysis, justification of specifications, reference

			andard or materials, container closure system and stability.			
	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 validation/verification of pro-			omitted analytical method verifice as well as drug product.	ication study reports for	
		STABILI	TY STU	DY DATA		
M/s. A. M.I.D.C Sitaglip Fluoride		M/s. AARTI DE M.I.D.C. Tarapu Sitagliptin Phosp Fluoride Industr	etformin Hydrochloride: /s. AARTI DRUGS LTD MANUFACTURING FACILITY Plot No. G– 60, .I.D.C. Tarapur, Tal Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA. tagliptin Phosphate Monohydrate: uoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning ovince -123000, China			
API Lo	t No.	L-D05-CP11422	2001 ME	F/12031196		
	otion of Pack iner closure system)	A white color o Blister packs in		ape, film coated tablet, Score on with leaflet	on one side in Alu-Alu	
Stability	y Storage Condition	Real time: 30°C Accelerated: 40°				
Time P	eriod	Real time: 6 mor				
Freque	ncy	Accelerated: 0, 3 Real Time: 0, 3,	: 0, 3, 6 (Months) 0, 3, 6 (Months)			
Batch N	No.	TTR037		TTR038	TTR039	
Batch S	Size	600 tablets		600 tablets	600 tablets	
Manufa	acturing Date	04/2023.		04/2023.	04/2023.	
No. of	Batches		03			
	DOCUMENTS / DATA	A TO BE PROVII	DED AL	ONG WITH STABILITY STU	DY DATA	
1.	Reference of previous applications with stability firm (if any)	1 1	NA			
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		THIRM has summitted convert table Lertificate of noth API			
3.			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.					
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.			
l	cs of Evaluator:					
S.no.	Section Observation	ons/Deficiencies/ comings	Short-	Reply	ÿ	

1.	3.2.S.4.1-		Firm submitted the specification and analytical
	3.2.S.4.2	procedure used for analysis of both drug	procedure of both drug substance.
		substances by drug product	
2.	3.2.S.4.1	manufacturer. Justify for using in-house complied drug	Firm raplied that This is a mistake from the
2.	3.2.3.4.1		Firm replied that This is a mistake from the procurement department though the parameters are
		manufacturing of drug product when the	similar to USP still we undertake that for
			commercial product manufacturing we will use
		phosphate is available in the USP.	USP monograph API.
3.	3.2.S.4.3	Submit analytical method verification	Firm submitted the same validation/verification
		report of both drug substance performed	report of drug substance as submitted for drug
		by the drug product manufacturer.	product.
4.	3.2.S.4.4	Submit batch analysis report of both drug	Submitted
		substance by drug product manufacturer.	
5.	3.2.S.7	Stability data of sitagliptin phosphate	Firm replied that "The accelerated stability study
		specified that the drug substance	of sitagliptin phosphate specified that the drug
		complied USP specification while the	substance complied USP is in API manufacturer
		other sections of drug substance part	DMF, we have communicated the matter to the
		claimed that the in-house complied	API manufacturer to address the subject, and we
		sitagliptin phosphate has been used in the	will communicate to the DRAP as will received
6.	3.2.P.5.1	manufacturing of drug product.	their reply". Firm replied that "The acceptance criteria of
0.	3.2.P.3.1	Specify the acceptance criteria of dissolution test in term of Q value, since	dissolution test in term of Q value are 80% in the
		the BP monograph of applied product	BP monograph of applied product".
		recommends the acceptance limit of	Dissolution acceptance limit need to be changed in
		dissolution test in terms of Q value.	accordance with BP monograph.
7.	3.2.P.5.2	Justify for not adopting the same assay	Firm replied that "The method adopted in the assay
		procedure as recommended by the BP	was that for dissolution of tablet due to isocratic
		monograph of Metformin and Sitagliptin	mode and give good results for both drug
		Tablets, since the submitted method is	substances. We undertake to use gradient method
		different from the procedure given in	in future for the assay of combination tablets"
		official monograph of BP.	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	Firm replied that "Sir please consider it valid. The
0.	3.2.1 .3.3	accordance with BP Monograph ,justify	same BP dissolution method in isocratic mode was
		how the applied product complied BP	used for the method verification of both substances
		specification.	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
	2200		monograph.
9.	3.2.P.8	Submit documents for the procurement	Firm submitted Form-6 of both drug substance.
		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.	
10	2.3.R.1.1	Provide Batch Manufacturing Record	Submitted.
		(BMR) of all stability batches.	
Decision	n: Deferred f	for submission of following shortcomings	<u>: </u>
			·

- 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				
	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 reauthorities	gulatory	USFDA approved		
	For generic drugs (me-to	o status)	Cavalor 125mg/5ml powder for oral suspension M/s Barrett Hodgson Pakistan (Pvt) Ltd (Reg No 030975)		
I I	Name and address of AP manufacturer.	I	China Union Chempharma (SuZhou) Co., Ltd No. 6 Jinzi Road, Lili Town , Wujiang District, Suzhou city, Jiangsu Province China		
	Module-II (Quality Over Summary)	all	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:		ice:	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 (Conditions & duration of studies)				
			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 valida product	tion study of	Firm has submitted analytical method verification study reports for drug substance and drug product.		
STABI	LITY STUDY DATA				
No. 6 Jinzi F			n Chempharma (SuZhou) Co., Ltd Road, Lili Town , Wujiang District, Suzhou city, Jiangsu ina		
API Lo	t No.	201211101			
_	Description of Pack (Container closure system) Amber glas		bottle		
Stability	3 6		0°C ± 2°C / 65% ± 5%RH : 40°C ± 2°C / 75% ± 5%RH		
		Real time: Accelerated:			

Frequency			Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)				
Batch No. TJI		TJI001	T.	JI002	TJI003		
Batc	h Size		325 Bottles	32	25 Bottles	325 Bottles	
Man	ufacturii	ng Date	08-2022	08	3-2022	08-2022	
	of Initia		28-08-2022	29	9-08-2022	30-08-2022	
No. o	of Batch	es	03	<u> </u>			
DOC	CUMEN	TS / DATA TO BE	E PROVIDED ALON	G W	TITH STABILITY ST	UDY DATA	
1.		nce of previous appability study data o	proval of applications f the firm (if any)		Not applicab	le	
2.	manufa		MP certificate of AP oncerned regulatory gin.	I	-	GMP certificate No JS2016063 d and Drug Administration da	
3.		ents for the procur al from DRAP (in	ement of API with case of import).		M/s Shawan Pharma	oan letter dated 11.08.2022 from accuticals, regarding borrowing hydrate 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.	attested	l respective docum	vill be supported by ents like chromatogra immary data sheets et		Submitted		
5.		ance Record of HI ail reports on prod	PLC software 21CFR uct testing	&	Provided		
6.	humidi		ger for temperature a ability chambers (rea		Provided		
Rem	arks of A	Assessor:			l		
	Sr.#	Observations		Re	eply Remarks		
	1	Valid approval of			rm has provided	Complied	
		Substance/Drug I	Manufacturing Good Manufacturing		armaceutical		
		Practice (GMP) of			Product License No Ju20160183 issued by		
			API manufacturer		iangsu Food and		
		issued by concern			rug Administration		
		•	try of origin to be		ted 15.03.2021 valid		
	2	provided. Regulatory status	of diluent (WFI) in		1 21.10.2025. e are not providing	Clarified	
		•	red with details of		y diluent with		
		manufacturer and	Registration No.	su	spension as		
				entioned in label of			
			pack that use boil water for				
					constitution		
	3		f container closure		A of glass bottle	Glass type,	
		system (Glass bo		ha	s been provided	specification/ quality	
		submit suitability pharmacopeia.	testing as per			tests (as per pharmacopeia) has not	
		pilarinacopeia.				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	
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	Batch No R220363 Exp date: 12-23 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
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	60ml. 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/noteguidance-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
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-F template. Firm has summarized information relat to nomenclature, structure, general properties solubility, physical form, manufacturers, description of manufacturing process and control specifications, analytical procedures and validation, batch analysis and justification specification, reference standard, container closure system and stability studies of drug substance a drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance darelated to nomenclature, structure, gener properties, solubility, physical form, manufactured description of manufacturing process and control specifications, analytical procedures and validation, batch analysis and justification specification, reference standard, container closus system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 18 mont Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for months
Module-III Drug Product:	The firm has submitted detail of manufacture description of manufacturing process and contro process validation studies, specifications, analytic procedure and validation studies batch analysis a

			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 valida	ation study of product				
STA	BILITY STUDY DATA					
Manı	ufacturer of API	China Union Chempharma (SuZhou) Co., Ltd No. 6 Jinzi Road, Lili Town , Wujiang District, Suzhou city, Jiangsu Province China				
API l	Lot No.	201211101				
	ription of Pack tainer closure system)	Amber glass bottle				
Stabi	lity Storage Condition	Real time: 30°C ± 2°C Accelerated: 40°C ± 2				
Time	Period	Real time: 6 months Accelerated: 6 month				
Frequ	uency	Accelerated: 0, 3,6 (Mor Real Time: 0, 3,6 (Mor		·		
Batcl	n No.	TJJ001	T.	JJ002	ТЈЈ003	
Batcl	n Size	325 Bottles	32	25 Bottles	325 Bottles	
Manı	ufacturing Date	09-2022	08	3-2022	09-2022	
Date	of Initiation	01-09-2022	02	2-09-2022	03-09-2022	
No. o	of Batches	03				
DOC	UMENTS / DATA TO BE	PROVIDED ALONG	W	TTH STABILITY STU	DY DATA	
1.	Reference of previous appropriate with stability study data of			Not applicable		
2.	Approval of API/ DML/Gl manufacturer issued by con authority of country of orig	ncerned regulatory		Firm has provided GMP certificate No JS20160635 issued by China Food and Drug Administration date 01.03.2019		
3.				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.	4. Data of stability batches will be supported by attested respective documents like chromatograms Raw data sheets, COA, summary data sheets etc.		s,	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		

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/d ocuments/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.

	submitted in the registration application.	-		
•	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 Cefaclor500mg		
	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-PE template. Firm has summarized information related to nomenclature, structure, general properties solubility, physical form, manufacturers, description of manufacturing process and controls		

	\ \frac{1}{2}		valida specif syster	specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.	
Module-III Di	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 Stud (Conditions &		Substance of Stability studies)	Real t	erated: 40°C ±	ions: C/65% ± 5%RH for 18 months = 2°C / 75% ± 5%RH for 6
			Batch	es: (KL200403,	, KL200404, KL200405)
Module-III Di	Module-III Drug Product: Pharmaceutical Equivalence and Dissolution Profile		descri proces proces justifi	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 was determined against Slate 500mg capsule (M/s Healthtek Pvt Ltd) Quality parameters such as identification, dissolution and Assay were compared.	
			agains Ltd) (
Analytical me	thod valida	ation 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 sys	stem)	Alu-Alu blister			
Stability Storage Cond	lition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%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		ТЈН003
Batch Size		2000 capsules	2000 caps	sules	2000 capsules
Manufacturing Date		09-2022	08-2022		08-2022
Date of Initiation		01-09-2022	02-09-202	22	03-09-2022
No. of Batches		03			

DOC	DOCUMENTS / DATA 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				

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	Complied
2	Provide details of comparator product (Manufacturer, Batch No and Exp date) under pharmaceutical equivalence study.	Healthtek Pvt Ltd) Batch No 002G	
3	Provide Drug-excipient compatibility study with Dimethicone Starch (being qualitatively different from innovator's formulation).		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 preregistration 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.

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
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)

all 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.	
nce:	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.	
Substance of Stability studies)	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 36 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months	
	Batches: (55021500223, 55021500233, 55021500243) 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.	
t:		
nce and Comparative	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).	
ntion study of product	Firm has submitted analytical method verification	
	study reports for drug substance and drug product.	
ACS Dobfar S.P.A Via	Marzabotto, 1,7/9-20871 Vimercate (MB	
00169		
Glass bottle		
Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / \Delta \text{ ccelerated: } 40^{\circ}\text{C} + 2^{\circ}\text{C}$		
Real time: 6 months	J 13 /0 ± 3 /0 X 11	
	Substance of Stability studies) t: acce and Comparative ACS Dobfar S.P.A Via 100169 Glass bottle Real time: 30°C ± 2°C / Accelerated: 40°C ± 2°C	

	Accelerated: 6 m	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

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	Duricef 125mg/5ml		
	product (Batch No and Exp date)	powder for oral		
	under pharmaceutical equivalence	suspension by GSK		
	study.			
		Batch No: 7D2J		
		Exp date: 11-24		
5	Provide details regarding volume	60ml of diluent to be	Pack size/ total volume	
	of diluent to be used for	used for reconstitution	(per pack) to be clarified.	
	reconstitution to achieve label	to achieve label claim		
	claim 125mg/5ml along with	125mg/5ml and	product's pack size is	
	weight/ml calculation with	250mg/5ml	90ml.	
	reference to innovator's product			
6	Provide commercial invoice of	Commercial invoice of	Complied	
	API (by Medisave	Cefadroxil (micronized)		
	pharmaceuticals) and clearance by	batch No 00169 cleared		
	I&E DRAP	by I&E DRAP dated		
		29.01.2020 in the name		
		of M/s Medisave		
		Pharmaceuticals.		
7	In use stability data (reconstituted	In use stability data	I - I	
	form) to be provided as per	(reconstituted form)	batch is provided	
	guidance document by EMA.	provided for 14 days.	performed at initial time	
	(https://www.ema.europa.eu/en/d		point.	
	ocuments/scientific-			
	guideline/note-guidance-use-			
	stability-testing-human-			
	medicinal-products en.pdf)			

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 Cefadroxil250mg
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

				1	
			justification of specification, container closure system and stability studies of drug product.		
	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).		
	Analytical method valida	ation study of product		Firm has submitted ar	nalytical method verification substance and drug product.
STA	BILITY STUDY DATA				
Man	ufacturer of API	ACS Dobfar S.P.A V	ia l	Marzabotto, 1,7/9-2087	1 Vimercate (MB
API	Lot No.	00169			
	ription of Pack tainer closure system)	Glass bottle			
Stabi	lity Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time	Period	Real time: 6 months Accelerated: 6 month			
Frequ	uency	Accelerated: 0, 3,6 (No. 1) Real Time: 0, 3,6 (No. 1)		· · · · · · · · · · · · · · · · · · ·	
Batcl	h No.	TJF001	TJ	F002	TJF003
Batcl	h Size	200 bottles	20	0 bottles	200 bottles
Man	ufacturing Date	07-2022	07	7-2022	07-2022
Date	of Initiation	27-07-2022	28	3-07-2022	29-07-2022
No. o	of Batches	03			
DOC	CUMENTS / DATA TO BE	PROVIDED ALONG	W	ITH STABILITY STU	DY DATA
1.	Reference of previous appropriate with stability study data of	* *		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.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		ıs,	Submitted	
5.	Compliance Record of HP audit trail reports on produ			Provided	_
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Provided		

Sr. #	Observations	Reply	Remarks
Ť	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/d ocuments/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

	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 gives
	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 Cefadroxil500mg
	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-I template. Firm has summarized information relat to nomenclature, structure, general propertic solubility, physical form, manufacturers, description of manufacturing process and controp specifications, analytical procedures and

			nalysis and justification of ce standard, container closure studies of drug substance and		
Module-III Drug Substan	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 (Conditions & duration of		months	ions: C / 65% ± 5%RH for 36 2°C / 75% ± 5%RH for 6		
Module-III Drug Produc	t:	description of manuf process validation stu procedure and valida justification of spe	itted detail of manufacturers, acturing process and controls, dies, specifications, analytical tion studies batch analysis and cification, container closure studies of drug product.		
Pharmaceutical Equivale Dissolution Profile	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	The values for f1 and f2 are in the acceptable range		
Analytical method valida	ation study of product		Firm has submitted analytical method verification study reports for drug substance and drug product.		
STABILITY STUDY DATA	T				
Manufacturer of API	ACS Dobfar S.P.A V	ia Marzabotto, 1,7/9-208	71 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° Accelerated: 40°C ±				
Time Period	Time Period Real time: 6 months Accelerated: 6 months				
Frequency	Accelerated: 0, 3,6 (Mo Real Time: 0, 3,6 (Mo				
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					
DOC	CUMENTS / DATA TO BE	PROVIDED ALONG	WITH STABILITY STU	DY DATA	
1.	1. Reference of previous approval of applications with stability study data of the firm (if any)		Not applicable	Not applicable	
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		API/51/H/2019 based 0 26/10/2018 issued by A	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.	3. Documents for the procurement of API with approval from DRAP (in case of import).		from M/s Medisave Ph	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 s,		
5.	5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Provided		
6.	1 1		l Provided		

Sr.#	Observations	Reply	Remarks
1	Approval of Drug Substance/Drug	Firm has provided	Complied
	Manufacturing License	copy of GMP	
	(DML)/Good Manufacturing	certificate No IT-	
	Practice (GMP) certificate of the	API/51/H/2023 based	
	Drug Substance / API	on inspection dated	
	manufacturer issued by concerned	26/05/2023 issued by	
	regulatory authority of country of	AIFA valid till 42	
	origin to be provided.	months from the date	
		of inspection	
2	Provide details of comparator	Duricef 500mg	
	product (Batch No and Exp date)	Capsule by GSK	
	under pharmaceutical equivalence		
	study.	Batch No: 649X	
		Exp date: 10/2024	
3	Provide Drug-excipient	Provided	API Cefadroxil
	compatibility study with Sodium		Monohydrate
	Lauryl Sulphate (being		(compacted) found
	qualitatively different from		compatible with SLS.
	innovator's formulation).		
4	Provide commercial invoice of	Commercial invoice	Complied
	API (by Medisave	of Cefadroxil	
	pharmaceuticals) and clearance by	(compacted) batch	
	I&E DRAP	No 00199 cleared by	
		I&E DRAP dated	
		29.01.2020 in the	
		name of M/s	
		Medisave	
		Pharmaceuticals.	

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.

	dress of Applicant / Marketing tion Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
Name, add	ress of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No 129, Sundar Industrial Estate Raiwind Road Lahore.
Status of th	ne applicant	☑ Manufacturer☐ Importer☐ Is involved in none of the above (contract given
GMP statu	s 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	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 a	pplication	□ New Drug Product (NDP)☑ Generic Drug Product (GDP)
Intended u	se of pharmaceutical product	□ Domestic sale□ Export sale☑ Domestic and Export sales
Dy. No. an	nd date of submission	Dy No: 21301 dated 29.08.2023
Details of	fee submitted	PKR 30,000/- Dated 03-08-2023
The propos	sed proprietary name / brand name	Ceftazidime Powder for Injection 250mg IM/I
	concentration of drug of Active attical ingredient (API) per unit	Each vial contains: Ceftazidime (as Ceftazidime Pentahydrate)
Pharmacot	herapeutic Group of (API)	Cephalosporin (Antibacterial)
Pharmaceu	itical form of applied drug	Powder for injection
Reference	to Finished product specifications	USP
Proposed I	Pack size	As per SRO
Proposed u	unit price	As per SRO
The status	in reference regulatory authorities	Ceftazidime 250mg powder for solution of injection IM/IV MHRA approved
For generic	c 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-Fitemplate. Firm has summarized information relations

		of manufacturing specifications, anal validation, batch a specification, referen	orm, manufacturers, description process and controls, ytical procedures and its nalysis and justification of ce standard, container closure studies of drug substance and	
Module-III Drug Substan	nce:	related to nomer properties, solubility, description of manuf specifications, anal validation, batch a specification, referen	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls,	
	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 Produc	t:	description of manuf process validation stu procedure and valida justification of spe	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 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.	
Pharmaceutical Equivaled Dissolution Profile	ence and Comparative	Fortum Injection 25 parameters such as a content weight, assa		
Analytical method valida	ation 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 Pha Address No 849 Dor , China		ict, Jinan, Shandong Province	
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 month Accelerated: 6 month			
Frequency	Frequency Accelerated: 0, 3,6 (M) Real Time: 0, 3,6 (M)			
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		Not applicable		
manufacturer issued by con	cerned regulatory	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.		
•		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		
attested respective document	nts like chromatograms,	Submitted		
•		Provided		
		Provided		
	Reference of previous appr with stability study data of Approval of API/ DML/GM manufacturer issued by con authority of country of original Documents for the procurer approval from DRAP (in case). Data of stability batches wis attested respective documents aw data sheets, COA, sun Compliance Record of HPI audit trail reports on product Record of Digital data logg humidity monitoring of stall	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. 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		

S #	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	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	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)	Justified
		Ceftazidime for injection=100/77x250 = 324.67mg	
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
	☐ Export sales ☐ 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-I template. Firm has summarized information relat to nomenclature, structure, general properti solubility, physical form, manufacturers, descripti of manufacturing process and control specifications, analytical procedures and validation, batch analysis and justification specification, reference standard, container closu system and stability studies of drug substance a drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance darelated to nomenclature, structure, gene properties, solubility, physical form, manufacture description of manufacturing process and control specifications, analytical procedures and validation, batch analysis and justification specification, reference standard, container closus 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

	Module-III Drug Product:		description of manufa process validation stu- procedure and validat justification of spec	tted detail of manufacturers, acturing process and controls, dies, specifications, analytical ion studies batch analysis and cification, container closure tudies of drug product.		
	Pharmaceutical Equivale Dissolution Profile	ence and Comparative		Pharmaceutical equivalence was determined again Fortum Injection 1g IM/IV by GSK, Qualiparameters such as appearance, LOD, Ph, averagement weight, assay, limit of pyridine, sodi carbonate were compared.		
	Analytical method valid	ation study of product			nalytical method verification substance and drug product.	
STA	BILITY STUDY DATA					
Man	ufacturer of API	Qilu Antibiotics Phar Address No 849 Don , China			ct, Jinan, Shandong Province	
API	Lot No.	2551LJ81JD				
Desc (Con	ription of Pack tainer closure system)	Glass vial				
Stabi	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm$				
Time	Period	Real time: 6 month Accelerated: 6 month				
Freq	uency	Accelerated: 0, 3,6 (1) Real Time: 0, 3,6 (1)				
Batc	h No.	TJP001	TJ	JP002	TJP003	
Batc	h Size	500 vials	50	00 vials	500 vials	
Man	ufacturing Date	01-2023	01	-2023	01-2023	
Date	of Initiation	05-01-2023	06	5-01-2023	07-01-2023	
No. o	of Batches	03				
DOC	CUMENTS / DATA TO BE	PROVIDED ALONG	W	ITH STABILITY STU	DY DATA	
1.	Reference of previous app with stability study data of			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 &	Provided
	audit trail reports on product testing	
6.	Record of Digital data logger for temperature and	Provided
	humidity monitoring of stability chambers (real	
	time and accelerated)	

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)	
Decis	throughout proposed shelf life and commitment submitted in the registrati	lidation of first three batches as per the commitment
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 Overa		rall Summary)	template. to nome solubility of mar specificat validation specificat	Firm has sunclature, st, physical for nufacturing ions, analy, batch arion, referenced stability s	QOS as per WHO QOS-PD mmarized information related ructure, general properties, rm, manufacturers, description process and controls, rtical procedures and its nalysis and justification of the standard, container closure studies of drug substance and
		nce:	related properties description specificat validation specificat	to nomenous, solubility, on of manufations, analya, batch arion, reference	detailed drug substance data clature, structure, general physical form, manufacturers, acturing process and controls, vical procedures and its nalysis and justification of ce standard, container closure radies of drug substance.
	Stability Studies of Drug (Conditions & duration		Real time Accelerate months	ed: 40°C ±	$2/65\% \pm 5\%$ RH for 36 months 2°C / 75% ± 5% RH for 6
				50001CJ81J 50005CJ81J-	-C,50003CJ81J-C C)
	Module-III Drug Produc	rt:	descriptio process va procedure justification	on of manufa alidation stude and validat on of spec	tted detail of manufacturers, acturing process and controls, dies, specifications, analytical ion studies batch analysis and cification, container closure rudies of drug product.
	Pharmaceutical Equivale Dissolution Profile	ence and Comparative	Fortum In parameter content v	njection 500 s such as a	alence was determined against omg IM/IV by GSK, Quality ppearance, LOD, Ph, average y, limit of pyridine, sodium ared.
	Analytical method valid	ation study of produc		Firm has submitted analytical method verification study reports for drug substance and drug product	
STABI	LITY STUDY DATA			3 3 3 3 5	
Manufacturer of API		Qilu Antibiotics Pha Address No 849 Do , China			ct, Jinan, Shandong Province
API Lot No.		2551LJ81JD			
Description of Pack (Container closure system)		Glass vial			
Stability Storage Condition Real time: 30°C ± Accelerated: 40°C					
Time P	Time Period Real time: 6 months Accelerated: 6 months				
Frequency Accelerated: Real Time:					
Batch N	No.	TJO001	TJO002		TJO003

Batch	n Size		500 vials	50	00 vials	500 via	ıls	
			-2023	01-2023	3			
Date of Initiation 02-01-2023 03-			3-01-2023	04-01-2	2023			
No. of Batches 03						l		
DOCUMENTS / DATA TO BE PROVIDED ALONG W					ITH STABILITY STUI	DY DAT	ГΑ	
1.	Reference of previous approval of applications with stability study data of the firm (if any)				Not applicable			
2.	manufacturer issued by concerned regulatory authority of country of origin.			Firm has provided copy SD20180660 dated 09/ Food and Drug Administration Februar 2023.	02/2018	issued by Chir		
3.	Documents for the procurement of API with approval from DRAP (in case of import).				Firm has provided loar Pharmaceuticals, regard Firm has provided come CIHMBC/04/12/311 dates purchase of 50Kg Cefts sodium carbonate USP Clearance certificate dates	ding bor amercial ated 01.1 azidime Batch N	rowing API. invoice no 11.2022 regardi pentahydrate w No 2551LJ81JE	ing ⁄ith
4.	atteste		Il be supported by nts like chromatogran nmary data sheets etc.		Submitted			
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing			ζ	Provided			
6.				d	Provided			
Rema	arks of	Assessor:		I				
	Sr. #	Observations		F	Reply		Remarks	
	1	Manufacturing Li Manufacturing certificate of the I manufacturer issu	rug Substance/Drug icense (DML)/Good Practice (GMP) Drug Substance / API ued by concerned y of country of origin	I I I I I I I I I I	Firm has provided co DML No 20160006 iss Food and Drug Adminis of Guangdong Province 04.11.2020 valid 03.11.2025	ued by stration	Complied	
	Regulatory status of diluent (WFI) in Pakistan is required with details of manufacturer and Registration No.		f	WFI 5ml by M/s obarmaceuticals Reg No 096744	Wimits	Provided		
			F	WFI 3ml, 5ml and 10ml Bosch pharmaceuticals Reg No 073420	by M/s			
	3	Whereas % of ceft CoA by DS manuf	ceftazidime base ch formula as 77%. azidime mentioned in facturer as 99.5% (on dium carbonatefree	e A	Assay of ceftazidime mentioned in CoA to manufacturer as 99.5% ceftazidime form ceftazidime pentahydrate codium carbonate Ceftazidime base = 9.10.1%-12.3%	by DS while is te with	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	Justified
		= 649.35mg 681.51mg/vial was mentioned due to typographic error.	
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/docume nts/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-P template. Firm has summarized information related to nomenclature, structure, general properties solubility, physical form, manufacturers, description of manufacturing process and control specifications, analytical procedures and validation, batch analysis and justification 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 darelated to nomenclature, structure, generoproperties, solubility, physical form, manufactured description of manufacturing process and controspecifications, analytical procedures and validation, batch analysis and justification specification, reference standard, container closury system and stability studies of drug substance.
Stability Studies of Drug Substance	Stability study conditions:

			Accelerated: 40° months	$^{\circ}$ C ± 2 $^{\circ}$ C / 75% ± 5%RH for 6		
				0003, GLY20004, GLY20005)		
Module-III Drug Product:			description of m process validatio procedure and va justification of	The firm has submitted detail of manufacturers description of manufacturing process and controls process validation studies, specifications, analytica procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.		
Pharmaceutical Equivaler Dissolution Profile		ence and Comparative	Glynvair 50mcg parameters such capsule weight, u content, assay,	equivalence was determined against g Rotacap by Highnoon Quality a as appearance, uniformity of uniformity of content weight, water microbial limit, uniformity of and aerodynamic assessment of e compared.		
	Analytical method valid	ation study of product	Firm has submi study reports for	tted analytical method validation drug product.		
STA	BILITY STUDY DATA					
Man	ufacturer of API		CARE PVT. LTD. U ., Palghar, 401506. M	NIT-1: PLOT NO. J-73, M.I.D.C Iaharashtra, India		
API	Lot No.	GLY/23002	GLY/23002			
	ription of Pack tainer closure system)	PA/Alu/PVC – Alu perforated unit-dose blister				
Stabi	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$				
Time	e Period	Real time: 3 months Accelerated: 3 months				
Freq	uency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)				
Batc	h No.	GLC-001	GLC-002	GLC-003		
Batc	h Size	2000 Cap	2000 Cap	2000 Cap		
Man	ufacturing Date	07-2023	07-2023	07-2023		
Date	of Initiation	05-07-2023	06-07-2023	07-07-2023		
No. o	of Batches	03				
DOC	CUMENTS / DATA TO BE	PROVIDED ALONG	WITH STABILITY	STUDY DATA		
1.	1. Reference of previous approval of applications with stability study data of the firm (if any)		Not applie	Not applicable		
2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		20/03/2020 issued	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.	3. Documents for the procurement of API with approval from DRAP (in case of import).		22.06.2023 where was purchased (B	d clearance certificate dated ein 0.02 Kg Glycopyrrolate (USP) atch 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.		Submi	tted			

5.	•		of HPLC software 21CFR	& Provided	
			product testing		
ó .			ta logger for temperature a		
	humidity monitoring of stability chambers (real			1	
		nd accelerated)		
Rema	rks of A	Assessor:			
nhale	er devic	e: Rotazon			
	Sr.#	Sections	Observations	Reply	Remarks
	1	3.2.P.2	Description of	Firm has provided details of	Complied
			Packaging (Container	inhalation device as follows:	1
			closure system) is to	Name:	
			be provided, also	Rotazon inhaler device	
			provide details of	Model: DL-D02	
			metered dose	Manufacturer:	
			inhalation device i.e	Taian Dalu Medical	
			Rotazon (name,	Instrument Co., Ltd West part of	
			model, manufacturer,	yitianmen street, Hi-tech zone,	
			shelf life) provided in	Taian, Shandong, China	
			pack.	Shelf life: 3 years	
	2	3.2.P.2.2.1	Provide details of	Glynvair 50mcg Rotacap by	Complied
	2	3.2.1 .2.2.1	comparator product	Highnoon	Complica
			against which	mgmioon	
			pharmaceutical	Batch No: 232146	
			equivalence study was	Exp date: 04/2025	
			performed. It should	Lxp date: 04/2023	
			reveal, brand name,		
			manufacturer, batch		
			no. and expiry date		
	3	3.2.P.8	Provide Stability data	Provided	Complied
	3	3.2.1.0		riovided	Complied
			including summary data sheet,		
			,		
			chromatograms, CoA		
			and raw data sheets		
			(both accelerated and		
			real time) for 6th		
			month period and		
		1	onward.		
ecis		pproved.	u will place fingt three	production batches on long te	um stability studi
				on accelerated studies for six	
			submitted in the registra		months as per tr
			_	alidation of first three batches as	per the commitme
			the registration applicati		F
284.			Applicant / Marketing	M/s Obsons Pharmaceuticals	209-S Quaid e azam
	Authorization Holder			Industrial estate, Kot Lakhpat	Lahore.
				M/a Obsana Dhamasaanti aala	200 C Ousid a azam
	Nam	e, address of l	Manufacturing site.	M/s Obsons Pharmaceuticals	209-3 Quald e azaili
	Nam	e, address of l	Manufacturing site.	Industrial estate, Kot Lakhpat	-
		e, address of l is of the applic	-		-
			-	Industrial estate, Kot Lakhpat ☑ Manufacturer	-
			-	Industrial estate, Kot Lakhpat	Lahore

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 Levofloxacin250mg
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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 48 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months Batches:(DC-004-1512001, DC-04-1512001, DC-004-1512003)

	Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile		description of manufacture process validation sture procedure and validation justification of spe	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 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).	
			Leflox 250mg tablet I (Batch No F03008) parameters such as it content uniformity, content and assay etc Flox 250mg Tablet (Flox 250mg Tablet (Flox 250mg Tablet) is Leflox 250mg tapakistan (Batch No Foundation 1.2) in Acetate Buffer (pH 6.8).		
	Analytical method valid product	ation/verification of	Firm has submitted an	nalytical method validation substance as well as drug	
STA	BILITY STUDY DATA		<u> </u>		
Manı	ıfacturer of API	Zhejiang East-Asia P	ejiang East-Asia Pharmaceutical Co Ltd, China		
API I	Lot No.	DC-004-1806013			
	ription of Pack tainer closure system)	Alu-Alu Blister (1x10's)			
Stabi	lity 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			
Frequ	iency	Accelerated: 0, 3, 6 (1) Real Time: 0, 3, 6,9,1	Months) 2,18 and 24 (Months)		
Batcl	ı No.	025	089	091	
Batcl	n Size	100,000 tab	100,000 tab	100,000 tab	
Manı	ıfacturing Date	10-2019	10-2019	10-2019	
Date	of Initiation	18-10-2019	24-10-2019	26-10-2019	
No. o	of Batches	03	,		
DOC	UMENTS / DATA TO BE	PROVIDED ALONG	WITH STABILITY STU	DY DATA	
1.	Reference of previous approval of applications with stability study data of the firm (if any)		Not applicable	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.			LEV181029-L dated 2 received quantity i.e. 3	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	Firm has provided copy of GMP certificate dated 29.07.2021 valid	Complied
	regulatory authority of country of origin to be provided	till 28th July 2026 issued by Sanmen Market Supervision Administration China	
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 sodium75mg /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: Stability Studies of Drug Substance (Conditions & duration of Stability studies)			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. 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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 Dissolution Profile	ee and Comparative		Not provided	
	Analytical method validati product	on/verification of		Firm has submitted analytical method validation study reports for drug product.	
STABI	LITY STUDY DATA				
Manufa	acturer of API	Aarti Drugs Limited, Plot No 109-D, Road No 29-Sion (East) Mumbai. India			
API Lo	t No.	DFS/11040129			
	otion of Pack iner closure system)	Amber glass ampoule 3ml			
Stabilit	y Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time P	eriod	Real time: 6 months Accelerated: 6 month	hs		
Freque	ncy	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch N	No.	DF-TB-001	Dl	F-TB-002	DF-TB-003
Batch S	Size	2500 ampoules	25	500 ampoules	2500 ampoules
Manufa	acturing Date	05-2023	05	5-2023	05-2023
Date of	initiation	18/05/2023	18	3/05/2023	18/05/2023
No. of Batches 03		03			
DOCU	MENTS / DATA TO BE P	ROVIDED ALONG	W	ITH STABILITY STU	UDY DATA
1.	Reference of previous approval of applications with stability study data of the firm (if any)			Not provided	
2.			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) had 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.		• • • • • • • • • • • • • • • • • • • •	
			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 30 th 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.

			process and controls, sp and its validation, bar	urers, description of manufacturing becifications, analytical procedures tch analysis and justification of standard, container closure system trug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile			substance at both acceler The accelerated stability 60% ± 5% RH for 6 Mc	fility study data of 3 batches of drug rated as well as real time conditions. If data is conducted at $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ on this. The real time stability data is $65\% \pm 5\%$ RH for 36 Months.
		description, composition manufacture, manufacture process validation prototof drug product, spectivalidation of analytic	ata of drug product including its on, pharmaceutical development, uring process and process control, ocols, control of excipients, control effications, analytical procedures, cal procedures, batch analysis, fications, reference standard or ure system and stability.	
		1	product against RUV Pharmatec Pakistan (Pv	armaceutical equivalence of their ASTAT 5mg Tablets by M/s t) Ltd. by performing quality tests Dissolution, and Uniformity of
		Firm has submitted CDP results of their product against RUVASTAT 5mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd. in 03 dissolution media.		
•		Method verification / validation studies have been submitted for drug substance as well as drug product.		
		STABILIT	Y STUDY DATA	
Manufac	turer of API	M/s Zhejiang Menovo Pharm	naceutical Co. Ltd. China	
API Lot		ROI-7-09210501		
Descripti (Containe system)	on of Pack er closure	Alu-Alu Blister		
Stability Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\%$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75$		
Time Per	riod	Real time: 6 Months Accelerated: 6 Months		
Frequency Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months))		
Batch No	Batch No. T-002		T-003	T-004
Batch Siz	ze	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 Ba	atches		03	
	DOCUMENTS	S / DATA TO BE PROVIDI	ED ALONG WITH STA	BILITY STUDY DATA
		rious approval of ility study data of the	Not p	rovided.

2	* *	Copy of GMP Certificate issued by Zhejiang Medical Products Services Centre for Information Publicity and Development, valid till Aug 24, 2023.
3	•	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.	
5		Audit trail reports on product testing has been submitted. Compliance Record of HPLC software 21CFR has not been submitted.
6		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

	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 $2^{\circ}C$ - $8^{\circ}C$ as per Drug Substance Manufacturer, hence the real time stability data of drug substance is conducted at $25^{\circ}C\pm2^{\circ}C/60\%$ RH $\pm5\%$ 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)	

- Requisite fee for pre-registration correction / Typographical Mistake.
- Justification / clarification for points below are needed;
- 0 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.

87.	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	Lic (Vol-II) dated 30 th June, 2020 contains section approfor: -	
		 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	
	Pharmacotherapeutic Group of (API)	(USP Specifications) C10AA07, HMG CoA reductase inhibitors	
	Pharmaceutical form of applied drug	Round, biconvex, brown colored film coated tablet, with both plain sides.	

Reference to Fi	nished product specifications	USP Specification
Proposed Pack	size	As per SRO
Proposed unit p	rice	As per SRO
The status in ref	ference regulatory authorities	CROSUVA 10mg Tablets, TGA Approved.
For generic dru	gs (me-too status)	RUVASTAT 10mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd.
Name and address	ess 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 (Qua	lity 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 Dru	g 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.
	s of Drug Substance 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 \pm 2°C / 60% \pm 5% RH for 6 Months. The real time stability data is conducted at 5°C \pm 3°C / 65% \pm 5% RH for 36 Months.
Module-III Dru	g Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Comparative D	Equivalence and issolution 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 meth product	nod validation/verification of	Method verification / validation studies have been submitted for drug substance as well as drug product.
	STABILITY	Y STUDY DATA
Manufacturer of API	M/s Zhejiang Menovo Pharm	naceutical Co. Ltd. China.
API Lot No.	ROI-7-09210501	

(Co	escription of Pack ontainer closure stem)	Alu-Alu Blister				
Stability Storage Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Condition Accelerated: $40^{\circ}\text{C} \pm 2$						
Tir	me Period	Real time: 6 Months Accelerated: 6 Mont				
Fre	equency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N	`			
Ba	tch No.	T-002	T-003	T-004		
Ba	tch Size	2500 Tablets	2500 Tablets	2500 Tablets		
Ma	anufacturing Date	09-2021	10-2021	10-2021		
Da	te of Initiation	09-2021	10-2021	10-2021		
No	o. of Batches		03			
DOCUMENTS / DATA TO BE PR			OVIDED ALONG WITH STA	BILITY STUDY DATA		
1. Reference of previous approval of applications with stability study data of the firm (if any)		Not provided.				
		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).		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 rec	cord for product testing.			
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)						

	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).

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.

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

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.

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.

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.

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.

 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.

xi. Please provide Compliance Record of HPLC Software 21CFR.

The firm has specified USP Test – I for performing Dissolution Test.

The firm has claimed that the analytical method was adjusted as per actual practice.

The firm has claimed that the analytical method was adjusted as per actual practice.

The firm has claimed that the analytical method was adjusted as per actual practice.

The firm has committed that USP Reference Standard will be used for standardization upon commercialization of drug product.

The firm has submitted that the recommended storage conditions for Rosuvastatin Calcium is $2^{\circ}C$ - $8^{\circ}C$ as per Drug Substance Manufacturer, hence the real time stability data of drug substance is conducted at $25^{\circ}C\pm2^{\circ}C/60\%$ RH \pm 5% RH.

Same as above.

The firm has stated that Comparator product was used as it was readily available.

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.

- 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 30 th 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 \pm 2°C / 60% \pm 5% RH for 6 Months. The real time stability data is conducted at 5°C \pm 3°C / 65% \pm 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,

4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Firm ha	as submitted analytical re	cord for product testing.	
			by AD Rosuva 21ZJ02	by of Clearance (vide No. 11450/2021 DRAP dated 02-08-2021) AD I&E DRAP, Lahore has been submitted for 1.5KGs suvastatin Calcium Batch No. ROI-7-09210501 vide Invoice No. ZJ027 dated 2021-6-30.	
		Copy of GMP Certificate issued by Zhejiang Medical Products Services Centre for Information Publicity and Development, valid till Aug 24, 2023.			
	Reference of previous approval of applications with stability study data of the firm (if any)			•	provided.
	DOCUMENTS	S / DATA TO BE PR	OVIDE	ED ALONG WITH STA	ABILITY STUDY DATA
No	o. of Batches			03	l
	te of Initiation	09-2021		10-2021	10-2021
	anufacturing Date	09-2021		10-2021	10-2021
	tch Size	2500 Tablets		2500 Tablets	2500 Tablets
	equency tch No.	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N	` '	T-003	T-004
	me Period	Real time: 6 Months Accelerated: 6 Mont		,	
Stability Storage Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$		C / 65% ± 5%RH 2°C / 75% ± 5%RH			
(Co	scription of Pack ontainer closure stem)	Alu-Alu Blister			
AF	PI Lot No.	ROI-7-09210501			
Ma	anufacturer of API			naceutical Co. Ltd. China	l.
	1*	STA	BILITY	Y STUDY DATA	
	Analytical meth	nod validation/verification	ation of		lidation studies have been submitted
					OP results of their product against ets by M/s Highnoon Laboratories edia.
Pharmaceutical Equivalence Comparative Dissolution Profile		and	product against ROSUL Laboratories Ltd. (Identification, Assay,	narmaceutical equivalence of their IN 20mg Tablets by M/s Highnoon by performing quality tests Dissolution, and Uniformity of	
				of drug product, spectivalidation of analytic justification of specification of specification.	ocols, control of excipients, control cifications, analytical procedures, cal procedures, batch analysis, fications, reference standard or sure system and stability.

5.	Compliance Record of HPLC software Audit trail reports on product testing has been submitt	ed.
	21CFR & audit trail reports on product Compliance Record of HPLC software 21CFR has not be	en
	testing submitted.	
6.	Record of Digital data logger for Firm has submitted record of digital data logger for temperature a	
	temperature and humidity monitoring of humidity monitoring of real time and accelerated stability chambe	rs.
	stability chambers (real time and	
	accelerated)	

	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).

- 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.

Tablets etc.

Cinaxipid Tablet 1mg, Axistart-K Tablets, Trubax

- 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.		, 11	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.	
		,	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 30 th 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:	studies of drug substance and drug product. Firm has submitted detailed drug substance data related to

				physical form, manufact process and controls, sp and its validation, ba	e, general properties, solubilities, curers, description of manufacturing pecifications, analytical procedures tch analysis and justification of standard, container closure system lrug substance.
		s of Drug Substance duration of Stability st	udies)	substance at both accelerated stability 75% ± 5% RH for 6 Mc	ility study data of 3 batches of drug rated as well as real time conditions. If data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ on this. The real time stability data is C / 65% \pm 5% RH for 36 Months.
	Module-III Dru	g Product:		description, composition manufacture, manufacture process validation protest of drug product, special validation of analytic justification of special products.	ata of drug product including its on, pharmaceutical development, uring process and process control, ocols, control of excipients, control effications, analytical procedures, cal procedures, batch analysis, fications, reference standard or our system and stability.
	Comparative Dissolution Profile		product against GAN Laboratories (Pakistan)	harmaceutical equivalence of their ATON 50mg Tablet by Abbott Ltd. by performing quality tests Dissolution, and Uniformity of	
				OP results of their product against et by Abbott Laboratories (Pakistan) edia.	
	Analytical method validation/verification of product		Method verification / val for drug substance as we		
		STA	BILIT	Y STUDY DATA	
Manufac	turer of API	M/s Prayosha Health	care Pvt	t. Ltd., Gujrat, India.	
API Lot	No.	ITP/004/21			
Descripti (Contain system)	on of Pack er closure	Alu-Alu Blister			
Stability Conditio	Storage	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time Per	riod	Real time: 6 Months Accelerated: 6 Month	ıs		
_ ·		Accelerated: 0, 3, (M Real Time: 0, 3, (Mon			
Batch No).	T-003		T-004	T-005
Batch Siz	ze	1500 Tablets		1500 Tablets	1500 Tablets
Manufac	turing Date	12-2021		12-2021	12-2021
Date of I	nitiation	12-2021		12-2021	12-2021
No. of B	atches			03	
	DOCUMENTS	S / DATA TO BE PR	OVIDE	ED ALONG WITH STA	BILITY STUDY DATA

1	. Reference of previous approval of applications with stability study data of the firm (if any)	I NOL DIOVIGEG.
2	* *	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.
(1)		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.	
5		Audit trail reports on product testing has been submitted. Compliance Record of HPLC software 21CFR has not been submitted.
6		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

	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 6 th Month Data of Stability Batches, supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Copy of 6 th Month Data of Stability Batches has been submitted.
viii.	Please provide Compliance Record of HPLC Software 21CFR. Please provide GMP status of the FPP	Certificate of 21CFR Compliance of HPLC Software has not been submitted.
13.	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.
х.	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.

- 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	Enteric coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole 20mg
N d d G G(ADV)	(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	
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ /

				75% ± 5% RH for 6 Mc	onths. The real time stability data is	
				conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$	$C / 65\% \pm 5\%$ RH for 36 Months.	
Module-III Drug Product:			description, composition manufacture, manufacture, process validation protection of drug product, specification of analytic justification of specification.	ata of drug product including its on, pharmaceutical development, aring process and process control, ocols, control of excipients, control cifications, analytical procedures, cal procedures, batch analysis, fications, reference standard or ure system and stability.		
	Pharmaceutical Equivalence Comparative Dissolution Profile		and	product against NEXU Pharma (Pvt) Ltd.	armaceutical equivalence of their M 20mg Capsules by M/s Getz by performing quality tests Dissolution, and Uniformity of	
					PP results of their product against as by M/s Getz Pharma (Pvt) Ltd.in	
	Analytical methoduct	nod validation/verifica	ation of	Method verification / val for drug substance as we	lidation studies have been submitted ell as drug product.	
		STA	BILITY	Y STUDY DATA		
Manut	facturer of API	M/s Vision Pharmac Islamabad.	euticals	(Pvt) Ltd. Plot No. 22-23	3, Industrial Triangle, Kahuta Road	
API L	ot No.	EMZ045893				
Descri (Conta system		Alu-Alu Blister				
Stabili Condi	•	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm$				
Time 1	Period	Real time: 6 Months Accelerated: 6 Month	hs			
Freque	ency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N)		
Batch	No.	099		123	129	
Batch	Size	70,000 Capsules		70,000 Capsules	70,000 Capsules	
Manuf	facturing Date	10-2019		11-2019	11-2019	
Date of	of Initiation	14-11-2019		20-11-2019	26-11-2019	
No. of	f Batches		03			
	DOCUMENTS / DATA 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 p	rovided.		
API manufacturer issued by concerned date		dated 3	Copy of GMP Certificate No. F.3-26/2019-Addl. Dir.(QA<-I) lated 31 st July 2019 valid for three years from the date of inspection 11 th February 2019) has been submitted.			
3. Documents for the procurement of API with approval from DRAP (in case of import).				•		

		EMZ045893, from M/s Vision Pharma, Islamabad has been submitted.
4	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.
4.	5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
(-	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers (January to June 2021).

- 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: 15μ L" whereas the applicant has mentioned "Temperature: Ambient, Flow rate: 1 mL/min and Injection volume: 20μ L". 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.
- Please provide valid approval of API/ DML/GMP Certificate of API manufacturer. The enclosed copy of xiii. GMP Certificate was valid till February, 2022.
- Please provide Reference of previous approval of applications with stability study data of the firm (if any). xiv.

cisio	ision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
1.	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 addre	ess of API manufacturer.	M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road Islamabad.	
	Module-II (Qua	llity 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 Dru	g 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.	
	•	s of Drug Substance duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 Months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 Months.	
	Module-III Dru	g Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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.	
	product		Method verification / validation studies have been submitted for drug substance as well as drug product.	
	STABILITY		Y STUDY DATA	
		M/s Vision Pharmaceuticals Islamabad.	(Pvt) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road	
API Lot No.		EMZ045482		
Description of Pack (Container closure system)		Alu-Alu Blister		
Stability Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\%$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75$		
		Real time: 6 Months Accelerated: 6 Months		
		· · · · · · · · · · · · · · · · · · ·	·	

Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No. 101		101	119	131	
Ba	tch Size	70,000 Capsules	70,000 Capsules	70,000 Capsules	
Ma	anufacturing Date	10-2019	11-2019	11-2019	
Da	te of Initiation	15-11-2019	23-11-2019	29-11-2019	
No	o. of Batches		03		
DOCUMENTS / DATA TO BE PR		OVIDED ALONG WITH STA	BILITY STUDY DATA		
1. Reference of previous approval of applications with stability study data of the firm (if any)		Not provided.			
1 1 * *		Copy of GMP Certificate No. F.3-26/2019-Addl. Dir.(QA<-I) dated 31st July 2019 valid for three years from the date of inspection (11th February 2019) has been submitted.			
•		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 batch by attested respecti chromatograms, Raw	ve documents like	Firm has submitted analytical re-	cord for product testing.	

testing Record

stability

accelerated)

summary data sheets etc.

of Digital

chambers

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

logger

time

for

Compliance Record of HPLC software Not submitted.

data

(real

21CFR & audit trail reports on product

i. 1.5.8 Reference in this section has been mentioned as "Generic Name: Diclofenac Potassium -50". Please justify.

temperature and humidity monitoring of humidity monitoring of real time and accelerated stability chambers

and (January to June 2021).

Firm has submitted record of digital data logger for temperature and

- 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: 15μ L" whereas the applicant has mentioned "Temperature: Ambient, Flow rate: 1 mL/min and Injection volume: 20μ L". 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 M/s Obsons Pharmaceuticals, 209-S Industrial Estate, **Authorization Holder** Kotlakhpat, Lahore. M/s Obsons Pharmaceuticals, 209-S Industrial Estate, Name, address of Manufacturing site. Kotlakhpat, Lahore. Status of the applicant ☐ Importer \square Is involved in none of the above (contract giver) Copy of GMP Certificate Ref. No. 15/2022-DRAP(AD-GMP status of the firm 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 Copy of GMP Certificate Ref. No. 15/2022-DRAP(ADfacility 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 Dihydrochloride5mg
	(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 the product was not discontinued or withdrawn for safety effectiveness reasons**).
For generic drugs (me-too status)	NEO-SEDIL 5mg Tablets of M/s SAMI Pharmaceutica (Pvt.) Limited.
Name and address of API manufacturer.	M/s HEMA Pharmaceuticals Pvt. Ltd, Plot No. 620, GID Ankleshwar, Gujarat, India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templated Firm has summarized information related to nomenclatural structure, general properties, solubilities, physical formanufacturers, description of manufacturing process at controls, specifications, analytical procedures and validation, batch analysis and justification of specification reference standard, container closure system and stabilistudies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubilities physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedurand its validation, batch analysis and justification 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 drasubstance at both accelerated as well as real time condition. The accelerated stability data is conducted at 40°C \pm 2°C 75% \pm 5% RH for 6 Months. The real time stability data conducted at 30°C \pm 2°C / 65% \pm 5% RH for 48 Months.
Module-III Drug Product:	Firm has submitted data of drug product including in description, composition, pharmaceutical development manufacture, manufacturing process and process control process validation protocols, control of excipients, control of drug product, specifications, analytical procedures validation of analytical procedures, batch analysis justification of specifications, reference standard materials, container closure system and stability.

	Pharmaceutical Equivalence Comparative Dissolution Profile		and	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			ion of Method verification / validation studies have been submitted for drug substance as well as drug product.		
	1*			Y STUDY DATA		
Manufac	cturer of API	M/s HEMA Pharmac	ceuticals	Pvt. Ltd, India.		
API Lot	No.	18LV0015				
Descript (Contain system)		Alu-Alu Blister				
Stability Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm$				
Time Pe	eriod	Real time: 6 Months Accelerated: 6 Mont				
Frequen	ncy	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N)		
Batch N	lo.	19B027		933	117	
Batch Si	ize	41,000 Tablets	500,000 Tablets		100,000 Tablets	
Manufac	cturing Date	02-2019		02-2019	02-2019	
Date of	Initiation	06-03-2019		04-03-2019	12-12-2019	
No. of B	Batches			03		
DOCUMENTS / DATA TO BE PR			OVIDE	ED ALONG WITH STA	BILITY STUDY DATA	
appli	Reference of previous approval of applications with stability study data of the firm (if any)		Not provided.			
API	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.			
with	•		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.			
by a	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.					
21Cl	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Not sul	bmitted.		
temp stabi	temperature and humidity monitoring of		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers (January to June 2021).			
Remark	ks 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: Piroxicam20mg
	(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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 Months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 60 Months.

	Module-III Drug Product:			description, composition manufacture, manufacture process validation protest of drug product, specification of analytic justification of specification	ata of drug product including its on, pharmaceutical development, uring process and process control, ecols, control of excipients, control effications, analytical procedures, cal procedures, batch analysis, fications, reference standard or ure system and stability.	
	Pharmaceutical Equivalence Comparative Dissolution Profile		and	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-		
	Analytical methoroduct	hod validation/verific	ation of	Day 5mg Tablets by M/s GSK in 03 dissolution media. n of Method verification / validation studies have been submitted for drug substance as well as drug product.		
	product	STA	BILIT	Y STUDY DATA	on as drag product.	
Ma	anufacturer of API	M/s Alcon Bioscience				
AF	I Lot No.	PCM/1027/20				
(Co	scription of Pack ontainer closure stem)	Alu-Alu Blister				
	bility Storage ndition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm$				
Time Period Real time: 6 Months Accelerated: 6 Months						
Fre	Frequency Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N)		
Ba	tch No.	19K141		19K146	19K151	
Ba	tch Size	50,000 Capsules		50,000 Capsules	50,000 Capsules	
Ma	nufacturing Date	11-2019		11-2019	11-2019	
Da	te of Initiation	06-11-2019		15-11-2019	28-11-2019	
No	. of Batches			03		
	DOCUMENTS	S / DATA TO BE PR	OVIDE	ED ALONG WITH STA	BILITY 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.		Drugs	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).		import by AD	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 ha	nas submitted analytical record for product testing.		

5.	Compliance Record of HPLC software Not submitted.
	21CFR & audit trail reports on product
	testing
	Record of Digital data logger for Firm has submitted record of digital data logger for temperature and
	temperature and humidity monitoring of humidity monitoring of real time and accelerated stability chambers
	stability chambers (real time and (January to June 2021).
	accelerated)

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 09 th 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 09 th 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	
	Defense es to Einich ed and duct and eificetions	White oblong tablet, plain on both sides.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	USP Specification As per SRO
	Proposed Pack size Proposed unit price	USP Specification As per SRO As per SRO
	Proposed Pack size Proposed unit price The status in reference regulatory authorities	USP Specification As per SRO As per SRO LYSTEDA 650mg Tablets, USFDA Approved.
	Proposed Pack size Proposed unit price	USP Specification As per SRO As per SRO
	Proposed Pack size Proposed unit price The status in reference regulatory authorities For generic drugs (me-too status)	USP Specification As per SRO As per SRO LYSTEDA 650mg Tablets, USFDA Approved. N/A M/s Hunan Dongting Pharmaceutical Co., Ltd., No. 16 Dongyan Road, Dehan, Changde, PC415001, Hunan

1. Reference of previous approval of applications with stability study data of the firm (if any)		Not p	rovided.		
			OVIDE	ED ALONG WITH STA	BILITY STUDY DATA
No. of B	atches			03	
Date of I	nitiation	03-2021		03-2021	03-2021
Manufac	turing Date	03-2021		03-2021	03-2021
Batch Si	ze	1000 Tablets		700 Tablets	800 Tablets
Batch No	Э.	Real Time: 0, 3, 6 (M	ionths)	TF-02	TF-03
Accelerated: 6 Months Frequency Accelerated: 0, 3, 6 (Months))			
Time Per		Accelerated: 40°C ± 2 Real time: 6 Months		% ± 3%KΠ	
system) Stability Conditio	_				
(Contain	ion of Pack er closure	HDPE Bottles			
API Lot		X2010609M		20, 20, 20,	
Manufac	turer of API			aceutical Co., Ltd., China	
	product			for drug substance as we Y STUDY DATA	
	Analytical method validation/verification of		LYSTEDA 650mg Table in 03 dissolution media.	P results of their product against ets by M/s Ferring Pharmaceuticals idation studies have been submitted	
	Pharmaceutical Comparative D	Equivalence issolution Profile	and		armaceutical equivalence of their DA 650mg Tablets by M/s Ferring
			description, composition manufacture, manufacture, manufacture, manufacture, manufacture, process validation protocolor drug product, spectivalidation of analytic justification of specification of specifications, container closs	•	
Stability Studies of Drug Substance (Conditions & duration of Stability stud		udies)	substance at both acceler The accelerated stability 75% ± 5% RH for 6 Mo	lity study data of 3 batches of drug ated as well as real time conditions. data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / nths. The real time stability data is $2/65\% \pm 5\%$ RH for 72 Months.	
				physical form, manufactor process and controls, sp and its validation, bat specification, reference and stability studies of de	

2	* *	Copy of GMP Certificate No. HN20160173 issued by China Food and Drug Administration, valid until 31/01/2021 has been submitted.
3	_	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.	
5	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6	temperature and humidity monitoring of	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).

The fol	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 stu		tudies)	The accelerated stability 75% ± 5% RH for 6 Mc	rated as well as real time conditions. If data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ on this. The real time stability data is $\frac{1}{65\%} \pm 5\%$ RH for 36 Months.
	Module-III Drug Product:			description, composition manufacture, manufacture process validation prototo of drug product, spectivalidation of analytic	ta of drug product including its on, pharmaceutical development, uring process and process control, ecols, control of excipients, control effications, analytical procedures, cal procedures, batch analysis, fications, reference standard or ure system and stability.
	Pharmaceutical Equivalence Comparative Dissolution Profile		and	product against TASMI	armaceutical equivalence of their Tablets 40mg of M/s Getz Pharma erforming quality tests (Assay, mity 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 meth product	nod validation/verifica	ation of	Method verification / val for drug substance as we	idation studies have been submitted ell as drug product.
		STA	BILITY	Y STUDY DATA	
Manu	facturer of API	M/s Jiangsu Zhongba	ang Phar	maceutical Co., Ltd. Chi	na.
API L	ot No.	D10011-20190905			
Descri (Conta systen		Alu-PVC Blisters			
Stabili Condi	•	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm$			
Time 1	Period	Real time: 6 Months Accelerated: 6 Month	hs		
Freque	ency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N)	
Batch	No.	TEL40-SB001		TEL40-SB002	TEL40-SB003
Batch	Size	1000 Tablets		1000 Tablets	1000 Tablets
Manu	facturing Date	12-2021		01-2022	01-2022
Date of	of Initiation	09-02-2022		09-02-2022	09-02-2022
No. of	f Batches			03	
	DOCUMENTS	S / DATA TO BE PR	OVIDE	ED ALONG WITH STA	BILITY STUDY DATA
1. Reference of previous approval of applications with stability study data of the firm (if any)			Not provided.		
			of Notice of GMP Ins 2020 has been enclosed.	pect results of Jiangsu Province	
3. Documents for the procurement of API C with approval from DRAP (in case of import).		4Kgs T		O(I&E) Lahore vide No. 2399/2020-	

2	by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
4	*	Firm has submitted audit trail reports on product testing. However, Compliance Record of HPLC software 21CFR has not been submitted.
(Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

	TO 6° ' ' / CI ' '	T
	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'.
х.	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	Telmisartan 80mg

	(USP Specifications)
Pharmacotherapeutic Group of (API)	C09CA07, Angiotensin II receptor blockers (ARBs), p
	White round shaped, biconvex core tablet plain from sides.
Reference to Finished product specifications	USP Specification
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
	Telmisartan 80mg Tablets of M/s Brillpharma (Ire Limited, Health Products Regulatory Authority (Ire Approved.
For generic drugs (me-too status)	TASMI Tablets 80mg of M/s Getz Pharma (Pvt.) Limit
	M/s Jiangsu Zhongbang Pharmaceutical Co., Ltd Shuanggao Rd., Gaochun, Nanjin, Jiangsu, China.
	Firm has submitted QOS as per WHO QOS-PD temporary firm has summarized information related to nomenclary structure, general properties, solubilities, physical manufacturers, description of manufacturing process controls, specifications, analytical procedures and validation, batch analysis and justification of specification reference standard, container closure system and states and drug product.
	Firm has submitted detailed drug substance data relat nomenclature, structure, general properties, solubil physical form, manufacturers, description of manufact process and controls, specifications, analytical process and its validation, batch analysis and justification specification, reference standard, container closure sy and stability studies of drug substance.
(Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of substance at both accelerated as well as real time condiction. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 75\% \pm 5\%$ RH for 6 Months. The real time stability d conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 Months.
	Firm has submitted data of drug product includin description, composition, pharmaceutical development manufacture, manufacturing process and process comprocess validation protocols, control of excipients, conforming product, specifications, analytical proceduration of analytical procedures, batch analytication of specifications, reference standard materials, container closure system and stability.
Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of product against TASMI Tablets 80mg of M/s Getz Ph (Pvt.) Limited by performing quality tests (A Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product ag
	TASMI Tablets 80mg of M/s Getz Pharma (Pvt.) Limit

product for drug substance as well as drug product.				
	STA	ABILITY STUDY DATA		
Manufacturer of API M/s Jiangsu Zhongbang Pharmaceutical Co., Ltd. China.				
API Lot No.	D10011-20190905			
Description of Pack (Container closure system)	(Container closure			
Stability Storage Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Condition Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$				
Time Period	Real time: 6 Months Accelerated: 6 Mont			
Frequency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N			
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		
DOCUMENT	S / DATA TO BE PR	ROVIDED ALONG WITH STA	BILITY 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.			pect results of Jiangsu Province	
3. Documents for the procurement of API with approval from DRAP (in case of import).			O(I&E) Lahore vide No. 2399/2020-	
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			cord for product testing.	
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)		humidity monitoring of real time		
Remarks of Evaluator				

	Deficiencies / Shortcomings	Response of the firm
i.	Please provide valid GMP status of the firm	The firm have submitted that they have applied for
	(FPP Manufacturer). The enclosed copy of	renewal of GMP and are waiting for Inspection.
	GMP Certificate was valid for two years	
	from the date of inspection (04-02-2020).	
	_	
		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.
- iv. Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.
- v. 3.2.P.5.2 Please specify the Dissolution Test 1, 2 or 3.
- 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.
- 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.
- 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.
- 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.
- x. Please provide Compliance Record of HPLC software 21CFR.
- xi. Please provide Reference of previous approval of applications with stability study data of the firm (if any).

GMP Certificate of API manufacturer issued by concerned Regulatory Authority of Country of Origin has not been submitted.

Submitted.

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.

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.

The firm have submitted Revised Method of Analysis for Elsart 40mg and 80mg Tablets.

Submitted.

Typographical error.

Container closure system is 'Alu-Alu Blisters'.

Submitted.

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

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 14 th 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 (USFD Approved).	
For generic drugs (me-too status)	CEFSPAN DS Suspension 200mg/5ml of M/s Barre Hodgson Pakistan (Pvt) Ltd.	
Name and address of API manufacturer.	M/s Pharmagen Ltd., Kot Nabi Bukhsh Wala, 34-Kı Ferozpur Road, Lahore.	
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templat Firm has summarized information related to nomenclatur structure, general properties, solubilities, physical form manufacturers, description of manufacturing process ar controls, specifications, analytical procedures and i validation, batch analysis and justification of specification reference standard, container closure system and stability	

				studies of drug substance	e and drug product.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: For a stability Studies of Drug Substance (Conditions & duration of Stability studies) To a stability Studies of Drug Substance (Conditions & duration of Stability studies) To a stability Studies of Drug Substance (Conditions & duration of Stability studies) To a stability Studies of Drug Substance (Conditions & duration of Stability studies) To a stability Studies of Drug Substance (Conditions & duration of Stability studies) To a stability Studies of Drug Substance (Conditions & duration of Stability studies) To a stability Studies of Drug Substance (Conditions & duration of Stability studies) To a stability Studies of Drug Substance (Conditions & duration of Stability studies) To a stability Studies of Drug Substance (Conditions & duration of Stability studies) To a stability Studies of Drug Substance (Conditions & duration of Stability studies) To a stability Studies of Drug Substance (Conditions & duration of Stability studies)		nomenclature, structure physical form, manufact process and controls, sp and its validation, bar	iled drug substance data related to e, general properties, solubilities, urers, description of manufacturing pecifications, analytical procedures tch analysis and justification of standard, container closure system rug substance.	
			substance at both acceler The accelerated stability 75% ± 5% RH for 6 Mc	allity study data of 3 batches of drug rated as well as real time conditions. It data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ on this. The real time stability data is $\frac{1}{2} = \frac{1}{2} = \frac{1}{2$	
			description, composition manufacture, manufacture process validation protocof drug product, spectivalidation of analytic	ta of drug product including its on, pharmaceutical development, uring process and process control, cols, control of excipients, control effications, analytical procedures, cal procedures, batch analysis, fications, reference standard or ure system and stability.	
			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 methoduct	nod validation/verifica	tion of	Method verification / validation studies have been submitted for drug substance as well as drug product. Y STUDY DATA	
		STA	BILIT		
Manufac	turer of API	M/s Pharmagen Ltd.,	Lahore		
API Lot	No.	00243/108/2021			
Descripti (Containe system)	on of Pack er closure	Amber Glass Bottle,	30ml.		
Stability Condition	•	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time Per	riod	Real time: 6 Months Accelerated: 6 Month	ıs		
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
	turing Date	01-2022		01-2022	01-2022
Date of I		01-2022		01-2022	01-2022
No. of Ba				03	
			OVIDE	ED ALONG WITH STA	BILITY STUDY DATA
		vious approval of ility study data of the		Not p	rovided.

2.	API manufacturer issued by concerned	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.	_	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.	
5.	<u> </u>	Firm has submitted audit trail reports on product testing. However certificate of 21CFR compliance of HPLC software has not been submitted.
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

	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	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°C to 8°C for upto 7	Typographical Error. 'After reconstitution, the suspension may be kept for 07 days at room temperature, or under, Refrigeration for upto 14 days.
	days'. Please clarify and submit supporting data (In-use stability studies).	

- 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.
- 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.
- viii. Furthermore, please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence.
- 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.
- 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.
- xi. Please justify (with supporting evidence) the quantity manufactured (100 Bottles) v/s quantity required for Development / Analysis / Stability Studies etc.
- xii. Please provide certificate of 21CFR compliance of HPLC software has not been submitted.
- xiii. Project Name in submitted Audit Trail Reports is 'Spril Capsule'. Please justify with supporting evidence.
- 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 that they have tested the said Batch as per USP Specifications and it complies as per USP Specifications.

The firm have submitted that Pharmaceutical Equivalence was performed against **CARICEF** Suspension DS, Batch No. 015H of Sami Pharmaceuticals.

Submitted.

Submitted.

The firm have submitted that the Finished Proudct is tested as per USP Specifications whereas the Alternate Methods are additionally for In-process testing.

The firm have submitted summary of quantity required for testing of stability batches.

Submitted.

The firm have submitted that since the Chromatographic conditions were same, therefore, instead of creating a new file, the same folder / file was used.

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 previou 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.

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 29 th 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	Strontium Ranelate 2g
	(Innovator's Specifications)
	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 p	orice	As per SRO		
The status in authorities	reference regulatory	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 Pharn	nEvo Pvt. Ltd.	
Name and manufacturer.	address of API	M/s Cadchem Laboratories Lin Derabassi, Distt Ajitgarh (Moha	nited, Village Jaula Khurd, Tehsil ıli), Punjab, India.	
Module-II Summary)	(Quality Overall	summarized information related properties, solubilities, physical manufacturing process and c procedures and its validation,	WHO QOS-PD template. Firm has to nomenclature, structure, general form, manufacturers, description of ontrols, specifications, analytical batch analysis and justification of rd, container closure system and ce and drug product.	
Module-III Dru	g Substance:	nomenclature, structure, generation, manufacturers, description controls, specifications, analytication analysis and justification of	drug substance data related to al properties, solubilities, physical on of manufacturing process and ical procedures and its validation, of specification, reference standard, ability studies of drug substance.	
	es of Drug Substance duration of Stability	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 Months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 Months.		
Module-III Dru	g Product:	composition, pharmaceutica manufacturing process and protocols, control of excipi specifications, analytical proc	rocess control, process validation ents, control of drug product, cedures, validation of analytical fication of specifications, reference	
	Equivalence and issolution Profile	Firm has submitted pharmaceutical equivalence of their product against ONITA 2g Sachet of M/s PharmEvo Pvt. Ltd.		
Analytical validation/verif	method ication of product	Method verification studies have been submitted for drug substance as well as drug product.		
	STA	BILITY STUDY DATA		
Manufacturer of API		ntories Limited, India.		
API Lot No.	SROD04210013			
Description of Pack (Container closure system) Aluminium Foil Sach		net		
Stability Storage Condition	Real time: 30°C ± 2°C Accelerated: 40°C ± 2			
Time Period	Real time: 6 Months Accelerated: 6 Month	ns		
Frequency	quency Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No.	T001	T002	T003	
Batch Size	2,000 Sachets	achets 2,000 Sachets 2,000 Sachets		

M	anufacturing Date	09/2022	09/2022	09/2022
Da	te of Initiation	09/2022	09/2022	09/2022
No	o. of Batches		03	
	DOCUMENTS	S / DATA TO BE PR	ROVIDED ALONG WITH STA	ABILITY STUDY DATA
1.	Reference of prevapplications with stab firm (if any)	* *		-
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			
3.	3. Documents for the procurement of API with approval from DRAP (in case of import).		import of 100Kgs Strontium SROD04210013/ SROD04210 Lahore vide No. 15293/2021 D of M/s Bio-Mark Pharmaceut	Ranelate (In-House), Batch No. 2014, cleared by AD(I&E) DRAP DRAP dated 12-10-2021 in the name cicals, Lahore has been submitted. documents regarding Loan of said
4.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			ecord for product testing.
5.	5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing			
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			

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 <i>Target Vs Innovator/Reference Product were tested for comparative dissolution profile and results referred.</i> 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.
	_	M/s Titlis Pharma (Private) Limited, 528 $-$ A, Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	
		☐ Importer
		\square 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 10 th 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	
	(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

			controls, specifications, analytication batch analysis and justification	on of manufacturing process and ical procedures and its validation, of specification, reference standard, ability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)		substance(s) at both accelerated Omeprazole: The accelerated s	tability data is conducted at $40^{\circ}C \pm$ nths. The real time stability data is	
			at 40° C $\pm 2^{\circ}$ C / $75\% \pm 5\%$ RH f	elerated stability data is conducted for 6 Months. The real time stability $2/65\% \pm 5\%$ RH for 36 Months.
I	Module-III Dru	g Product:	composition, pharmaceutica manufacturing process and protocols, control of excipi specifications, analytical pro-	rocess control, process validation ents, control of drug product, cedures, validation of analytical fication of specifications, reference
	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.	
			ts of their product against RISEK of M/s Getz Pharma (Pvt.) Limited	
Analytical method validation/verification of product			Method verification / validatio drug substance as well as drug p	n studies have been submitted for
	variation, vern		BILITY STUDY DATA	and the second s
_		etrochem API Private Limited, I e: M/s Solvay Peroxythai Limite		
API Lot No.		OME-P/22096 / MTP 22921		
Description of Pack (Container closure system)		Aluminium foil sache	et	
Stability Storage Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Condition Accelerated: $40^{\circ}\text{C} \pm 10^{\circ}$				
Time Period Real time: 6 Months Accelerated: 6 Month		18		
Frequency Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (
Batch No. TM -02		TM -03	TM -04	
Batch Size	e	100 Sachet	100 Sachet	100 Sachet
Manufactu	uring Date	DEC – 2022	DEC - 2022	DEC - 2022
Date of In		30-12-2022	30-12-2022	30-12-2022
No. of Bat			03	
l l	DOCUMENTS	S / DATA TO BE PR	OVIDED ALONG WITH STA	BILITY 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.		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.

	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.	
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.

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 10 th 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 10 th , 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	
		(Innovator's Specifications)

Pharmacotherapeutic Group of (API)	A02BC51, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflicience (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 (Pv Limited.
Name and address of API manufacturer.	Omeprazole: M/s Metrochem API Private Limited, Unit-IV: P No.: 34B, 40B & 60B, Jawaharlal Nehru Pharmacity, Thana Village, Parawada Mandal, Visakhapatnam District-53102 Andhra Pradesh, India. Sodium Bicarbonate: M/s Solvay Peroxythai Limited, 1, I-3
	Road, Tambol Map Ta Phut, Amphur Muang, Rayong 2115 Thailand.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, gene properties, solubilities, physical form, manufacturers, description manufacturing process and controls, specifications, analytic procedures and its validation, batch analysis and justification specification, reference standard, container closure system a stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubilities, physic form, manufacturers, description of manufacturing process a controls, specifications, analytical procedures and its validation batch analysis and justification of specification, reference standa 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 dr substance(s) at both accelerated as well as real time conditions. Omeprazole: The accelerated stability data is conducted at 40°C 2°C / $75\% \pm 5\%$ RH for 6 Months. The real time stability data conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 24 Months.
	Sodium Bicarbonate: The accelerated stability data is conduct at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 Months. The real time stabil data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 Months.
Module-III Drug Product:	Firm has submitted data of drug product including its description composition, pharmaceutical development, manufacturing process and process control, process validating protocols, control of excipients, control of drug produst specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, referent standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their produced against RISEK INSTA Sachet 40mg + 1680mg of M/s Getz Pharm (Pvt.) Limited.

				tts of their product against RISEK of M/s Getz Pharma (Pvt.) Limited
		Method verification / validation studies have been submitted for drug substance as well as drug product.		
	-	STA	ABILITY STUDY DATA	
Ma	anufacturer of API	_	Ietrochem API Private Limited, I.e: M/s Solvay Peroxythai Limite	
AF	PI Lot No.	OME-P/22096 / MT	P 22921	
(C	escription of Pack ontainer closure stem)	Aluminium foil sach	et	
	ability Storage ondition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm$		
Tiı	me Period	Real time: 6 Months Accelerated: 6 Mont	hs	
Fre	equency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N	· · · · · · · · · · · · · · · · · · ·	
Ba	tch No.	TM -06	TM -07	TM -08
Ba	tch Size	250 Sachet	250 Sachet	250 Sachet
Ma	anufacturing Date	DEC – 2022	DEC - 2022	DEC – 2022
Da	te of Initiation	30-12-2022	30-12-2022	30-12-2022
No	o. of Batches		03	
	DOCUMENT	S / DATA TO BE PR	OVIDED ALONG WITH STA	BILITY STUDY DATA
1. Reference of previous approval of applications with stability study data of the firm (if any)		+ Metformin).	& 5mg/1000mg (Dapagliflozin s, Linet 2.5mg/850mg Tablets	
			Linet 2.5mg/1000mg Tablets	
		= -	rtificate No. L.Dis.No: E- 1862189 11-2022, valid for 01 year from the d.	
			Certificate of Manufacturer Ref. No. AN 2023, Valid until December 31 ,	
3. Documents for the procurement of API with approval from DRAP (in case of import).		Powder (Batch No. OME-P Chemicals Pvt. Ltd., Lahore approval from DRAP for		
				Invoice No. L-8877 dated 15-02- ium Bicarbonate (MTP 22921) has
4.	Data of stability bate by attested respect		Firm has submitted analytical re	cord for product testing.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
4	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)	

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.
- Name, address of Applicant / M/s Pearl Pharmaceuticals, Plot No. 204, Street No.1, I-10/3 Industrial Area, Islamabad.

site.	M/s Pearl Pharmaceuticals, Plot No. 204, Street No.1, I-10, 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<-1)-dated 28 th February, 2023 valid for two years till 02-11-2024, h been submitted.
Evidence of approval of manufacturing facility	Copy of Section Approval Letter No. F.1-18/90-Lic(Vol-III) date 21st February, 2023 has been submitted, mentioning Ampou 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	
	(BP Specifications)
Pharmacotherapeutic Group of (API)	
11 0	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 h summarized information related to description, composition pharmaceutical development, manufacture, manufacturing proceand process control, process validation protocols, control excipients, control of drug product, specifications, analytic procedures, validation of analytical procedures, batch analysis justification of specifications, reference standard or material
	container closure system and stability studies of drug product.
Module-III Drug Substance:	container closure system and stability studies of drug product. N/A Firm has submitted that the Drug Substance for Sterilized Water Injection is Water for Injection Produced and filled on same day.

`	studies) Module-III Drug Product:		· ·	g Substance for Sterilized Water for Produced and filled on same day
M			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
	harmaceutical omparative Di	Equivalence and issolution Profile	Firm has submitted Comparative with Water for Injection from S	ve Analysis Report of their Product urge Laboratories.
	nalytical alidation/verif	method ication of product	Method verification studies hav	e been submitted for drug product.
		STA	BILITY STUDY DATA	
Manufactur	rer of API	N/A		
API Lot No).	N/A		
Description (Container system)	of Pack closure	Clear glass ampoules	3.	
Stability Condition	Storage	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$		
Time Perio	d	Real time: 6 Months Accelerated: 6 Month	hs	
Frequency		Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N		
Batch No.		WFI - 01	WFI - 02	WFI - 03
Batch Size		1320 Ampoules	1320 Ampoules	1320 Ampoules
Manufactur	ring Date	03 - 2023	03 - 2023	03 - 2023
Date of Init	tiation	03 - 2023	03 - 2023	03 - 2023
No. of Batc	ches		03	
D	OCUMENTS	S / DATA TO BE PR	OVIDED ALONG WITH STA	BILITY STUDY DATA
		ious approval of ility study data of the	Not p	rovided.
API ma	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			
with ap	B. Documents for the procurement of API with approval from DRAP (in case of import).]	N/A
by atte	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 re	cord 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	Firm has submitted record of digital data logger for temperature and
	temperature and humidity monitoring of			onitorin	g of	humidity monitoring of real time and accelerated stability chambers.	
	stability	ch	nambers	(real	time	and	
	accelerate	ed)					

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

	Deficiencies / Shortcomings	Response of the firm	
i.	Label claim has been mentioned as 'Each	The firm have submitted corrected label claim as:	
	Ampoule Contains: Water for Injection	Each Ampoule Contains: Sterile Water for Injection	
	5ml', whereas the same needs to be	5ml.	
	corrected as 'Each Ampoule Contains:		
	Sterile Water for Injection 5ml'.		
ii.	3.2.P.5.3 Analytical Method Verification	Not submitted.	
	has not been submitted in this Section.		
iii.	Please provide evidence (along with Batch	Submitted.	
	details) for Reference / Innovator pack used		
	for Comparative Analysis.		
iv.	Please provide Compliance Record of	N/A	
1,,	HPLC software 21CFR & audit trail reports	1011	
	on product testing.		
	-		
v.	Please provide Data of 06 th Month Testing	Submitted.	
	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 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.	7	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<-1)-20 dated 28 th 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 21 st 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	☐ Export sale
Dy. No. and date of submission	☑ Domestic and Export salesDy. 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	<u> </u>
Pharmacotherapeutic Group of (API)	
* * * * * * * * * * * * * * * * * * * *	Clear colorless liquid filled in clear glass ampoules.
	BP Specification
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
	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 h summarized information related to description, composition pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control excipients, control of drug product, specifications, analytic procedures, validation of analytical procedures, batch analysis justification of specifications, reference standard or material 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 f 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 days on stability is needed.
Module-III Drug Product:	Firm has submitted data of drug product including its description composition, pharmaceutical development, manufacturing process and process control, process validation protocols, control of excipients, control of drug product specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, referent standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Comparative Analysis Report of their Produ with Water for Injection from Surge Laboratories.

	STABILITY STUDY DATA				
Ma	anufacturer of API	N/A			
AF	PI Lot No.	N/A			
Description of Pack (Container closure system)		S.			
	ability Storage ondition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm$			
Tiı	me Period	Real time: 6 Months Accelerated: 6 Mont	hs		
Fre	equency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N			
Ba	tch No.	WFI - 01	WFI - 02	WFI - 03	
Ba	tch Size	857 Ampoules	857 Ampoules	857 Ampoules	
Ma	anufacturing Date	03 - 2023	03 - 2023	03 - 2023	
Da	te of Initiation	03 - 2023	03 - 2023	03 - 2023	
No	o. of Batches		03		
	DOCUMENTS	S / DATA TO BE PR	OVIDED ALONG WITH STA	ABILITY STUDY DATA	
1.	Reference of previous approval of applications with stability study data of the firm (if any)		Not p	provided.	
2.	Approval of API/ DM API manufacturer is regulatory authority o	ssued by concerned]	N/A	
3.	Documents for the pwith approval from 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 re	cord for product testing.	
5.	Compliance Record 21CFR & audit trail testing		Not submitted.		
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and			gital data logger for temperature and accelerated stability chambers.	

accelerated)

	Deficiencies / Shortcomings	Response of the firm	
i.			
		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 06 th 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

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

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. New Drug Product (NDP) Generic Drug Product (GDP)	
	Status of application		
	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: Apixaban2.5mg	
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-PI 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 it 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 batche of drug substance at both accelerated as well as reatime conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.	
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols control of excipients, control of drug product specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of	

			specifications, refere container closure syste	nce standard or materials, em and stability.
	Pharmaceutical Equival Dissolution Profile	lence and Comparativ	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 va	alidation/verification	of Firm has submitted study reports for drug	analytical method validation product.
		STABILITY S	TUDY DATA	
Manu	nfacturer of API	Changzhou Pharmacet Jiangsu Province 2130		odong East Road, Changzhou,
API I	Lot No.	ZSAP210402		
	ription of Pack tainer closure system)	Alu-PVC Blister		
Stabi	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequ	iency	Accelerated: 0, 3, 6 (No Real Time: 0, 3, 6 (Mo		
Batch	n No.	T-0010TBA	T-0011TBA	T-0012TBA
Batch	n Size	2000 Tablet	2000 Tablet	2000 Tablet
Manı	facturing Date	02-2022	02-2022	02-2022
Date	of Initiation	28-03-2022	28-03-2022	28-03-2022
No. c	f Batches		03	
	DOCUMENTS / DATA	TO BE PROVIDED	ALONG WITH STABII	LITY STUDY DATA
1.	Reference of previous appr stability study data of the f		h Not submitted.	
2.	Approval of API/ DML/O manufacturer issued by authority of country of orig	concerned regulator	y 22-10-2021 issued by Administration., valid to	py of GMP Certificate dated y Jiangsu Changzhou Drug till 21-10-2025. The certificate s operating at satisfactory level
3.	Documents for the proc approval from DRAP (in ca		cleared on 17-08-2021	copy of commercial invoice specifying 1Kg of Apixaban. by AD (I&E) DRAP, Lahore.
4.	Data of stability batches attested respective docume Raw data sheets, COA, sur	ents like chromatograms		llytical record for product
5.	Compliance Record of HF audit trail reports on produc			tificate of 21 CFR compliance long with audit trail report for

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

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: Apixaban5mg
	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 (Reg.No. 105619)
Name and address of API manufacturer.	Changzhou Pharmaceutical Factory, No. Laodong East Road, Changzhou, Jiangsu Provi 213018, P.R. China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS template. Firm has summarized information relation nomenclature, structure, general propert solubilities, physical form, manufacture description of manufacturing process and contrapecifications, analytical procedures and verification/validation, batch analysis justification of specification, reference stand container closure system and stability studies drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance of related to nomenclature, structure, generally properties, solubilities, physical for manufacturers, description of manufacture process and controls, specifications, analytic procedures and its verification, batch analysis justification of specification, reference standard container closure system and stability studies drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batc of drug substance at both accelerated as well as time conditions. The accelerated stability data conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for months. The real time stability data is conducted $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.
Module-III Drug Product:	Firm has submitted data of drug product includits description, composition, pharmaceut development, manufacture, manufacturing product and process control, process validation protoc control of excipients, control of drug product specifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or materic container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence their product against the innovator's product Elic 5mg Tablet marketed by Bristol My Squibb/Pfizer EEIG. Firm has submitted CDP results of their product against the innovator's product Eliquis 5mg Tallin 3 dissolution media. The value for similar factor is in the acceptable range.
Analytical method validation/verification of product	Firm has submitted analytical method valida study reports for drug product.

			STABILITY ST	TUDY DATA			
Man	ufacture	er of API	Changzhou Pharmaceut Jiangsu Province 21301		518 Laodong East Road, Chan	gzhou,	
API	Lot No.		ZSAP210402	ZSAP210402			
	cription ntainer c	of Pack losure syster	n) Alu-PVC Blister	Alu-PVC Blister			
Stab	ility Sto	rage Conditi	on Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / \text{Accelerated: } 40^{\circ}\text{C} \pm 2^{\circ}\text{C}$				
Time	e Period		Real time: 6 months Accelerated: 6 months				
Freq	uency		Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mo				
Batc	h No.		T-0003TBB	T-0004TBB	T-0005TBB		
Batc	h Size		2000 Tablet	2000 Tablet	2000 Tablet		
Man	ufacturi	ng Date	03-2022	03-2022	03-2022		
Date	of Initi	ation	26-04-2022	26-04-2022	26-04-2022		
No.	of Batch	nes		03	-		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STU					FABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any) Not submitted.						
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			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.			AP (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.	atteste	d respective	batches will be supported by documents like chromatograms, OA, summary data sheets etc.	Firm has submitted analytical record for product testing.			
5.			d of HPLC software 21CFR & n product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.			
6.	humid		data logger for temperature and ng of stability chambers (real ed)				
Rem		Evaluatorx		•			
	Sr. No.	Sections	Observations/Deficiencies/ Sh	nort-comings	Reply of applicant		
	4.	1.6.5	Validity of GMP certificate or manufacturer is 21-10-2021 certificate of drug substance m be submitted.	. Valid GMP	Submitted		
	5.	3.2.P.8	Results of real time and account studies for six-month time submitted.		Submitted		
	6.	3.2.P.8	Documents for the procureme approval from DRAP shall be s		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.

5.	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 Acid6.48mg 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 Over	all 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 Substar	nce:	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 (Conditions & duration of		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} \ / \ 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} \ / \ 65\% \pm 5\%$ RH for 48 months.
Module-III Drug Produc	t:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equival Dissolution Profile	ence and Comparative	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 va	alidation/verification of	Firm has submitted analytical method validation study reports for drug product.
	STABILITY STU	
Manufacturer of API		nceutical Co. Ltd. Fluoride Industrial Park, Fumeng n City, Liaoning Province 123000, P.R. China.

API Lot No.			L-IG-20211005-D01-IC	L-IG-20211005-D01-IG06-03			
	ription of	of Pack losure syste	Alu-Alu Blister				
Stabi	lity Sto	rage Condi		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time	Period		Real time: 6 months Accelerated: 6 months				
Frequ	uency		Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mor	,			
Batcl	n No.		T-0002TBC	T-0003TBC	T-0004TBC		
Batcl	n Size		2000 Tablet	2000 Tablet	2000 Tablet		
Manı	ufacturi	ng Date	03-2022	04-2022	04-2022		
Date	of Initia	ation	10-05-2022	10-05-2022	10-05-2022		
No. o	of Batch	ies		03			
	DOC	CUMENTS	/ DATA TO BE PROVIDED A	LONG WITH STA	ABILITY 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 License No. 2015 valid till 17-11-2027				0233		
3.	Documents for the procurement of API with approval from DRAP (in case of import).						
4.	attested	d respective	batches will be supported by documents like chromatograms, COA, summary data sheets etc.				
5.			rd of HPLC software 21CFR & on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.			
6.	humidi		ring of stability chambers (real	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.			
Rem		Evaluator					
	Sr.	Sections	Observations/Deficiencies/ Sho	ort-comings	Reply of applicant		
	No. 1. 1.6.5 Validity of GMP certificate of manufacturer is 23-08-2023. Valor of drug substance manufacturer relevant regulatory authority origin shall be submitted.			lid GMP certificate rer issued by the of the country of	issued by Liaoning Provincial Food and Drug Administration		
	2.	2.3.S.4 & 3.2.S.4	Specifications of drug substa content limit for LPGA and Ertu	gliflozin LPGA.	Revised specifications, analytical method and CoA are submitted.		
	3.	3.2.S.7	Long term stability studies of t shall be submitted as per Zone-I	•	Submitted.		
	4.	3.2.P.5	Specifications do not incl Ertugliflozin LPGA and LPGA.	ude content of Justify.	revised specifications.		
	5.	3.2.P.8	Results of real time and acceleration for six-month time point shall be		Submitted.		

6.	3.2.P.8	Documents for the procurement of API with	ADC attested invoice /
		approval from DRAP shall be submitted.	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.

6.	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. Firm has submitted copy of letter of DML renewal wef 07-01-2016 specifying Tablet (General) section.			
	Evidence of approval of 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 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: Apixaban2.5mg			
	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					
	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 Over	all 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 Substan	ice:	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 (Conditions & duration o		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ 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 Equival Dissolution Profile	ence and Comparative	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 va product	llidation/verification of	Firm has submitted analytical method validation study reports for drug product.
		STABILITY STU	UDY DATA
Manufa	cturer of API	Glenmark Life Sciences District Bharuch.	Ltd, Plot 3109, GIDC, Industrial Estate, Ankleshwar,
API Lot	t No.	802008793	
_	tion of Pack ner closure system)	Alu-Alu Blister	
Stability	y Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$	

Time	Time Period		Real time: 6 months Accelerated: 6 months				
Freq	uency		Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mo				
Batc	h No.		T-001	T-002	T-003		
Batc	h Size		5000 Tablet	5000 Tablet	5000 Tablet		
Man	ufacturing	Date	10-2021	10-2021	10-2021		
Date	of Initiation	on	20-10-2021	24-10-2021	24-10-2021		
No.	of Batches			03			
	DOCU	MENTS / D	DATA TO BE PROVIDED A	LONG WITH STA	BILITY 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.			testing.			
5.			of HPLC software 21CFR & product testing	for the HPLC system along with audit trail report for product testing.			
6.	humidity	Digital da monitoring accelerated)	g of stability chambers (real	Firm has submitted temperature and hur accelerated stability	record of digital data logger formidity monitoring of real time and chambers.		
Rem	arks of Ev	aluator ^{xxiii}	1				
	Sr.No.	Sections 1.3.4	Observations/Deficiencies/ DML of drug product manufa 06-01-2021. Copy of valid DRAP shall be submitted.	acturer was valid till	Reply of applicant Copy of valid DML No. 000333 renewed w.e.f. 07-01-2021 is submitted.		
	2.	1.6.5	manufacturer issued by co- authority of country of origin as the submitted DML was va	n shall be submitted alid till 31-12-2023.	Copy of GMP certificate valid till 05/06/2025 is submitted.		
	3.	3.2.S.4.1	Specifications of drug substated different from those given substance in 3.2.S.4.4. Justif	in CoA of drug y.	Revised specifications submitted.		
	4.	3.2.S.4.4	CoA of drug substance g product manufacturer for 802008793 (Mfg 11-20, Exp submitted.	Batch Number biry 12-24) shall be	Submitted.		
	5.	3.2.S.7	Long term stability studies conducted at Zone IV-a con the claimed shelf life shall be	ditions throughout	Submitted.		

	6.	3.2.P.8			Submitted.	
Decis •	propos the reg Manus	facturer wi sed shelf lif gistration a facturer w	ill place first three production batches on long term stability studies throughout fe and on accelerated studies for six months as per the commitmentsubmitted in application. ill perform process validation of first three batches as per the commitment registration application. Applicant / Marketing M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi. Manufacturing site. M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi. Cant ⊠ Manufacturer □ Importer □ Is involved in none of the above (contract giver) Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 16-02-2024.			
307. Name, address of Applicant / Marketing Authorization Holder Name, address of Manufacturing site. M/s Shaigan Pharmaceuticals (Pvt) I M/s Adyala Road Post C				14 km Adyala	• • • • • • • • • • • • • • • • • • • •	
		Daghal,				
	Status	of the applic	cant	☐ Importer		ct giver)
	GMP status of the firm					
	Eviden	ce of approv	val of manufacturing facility	Firm has submitte	d copy of letter of DML	renewal

Status of application

Intended use of pharmaceutical product

The proposed proprietary name / brand name

Reference to Finished product specifications

The status in reference regulatory authorities

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit

Pharmacotherapeutic Group of (API)

Pharmaceutical form of applied drug

For generic drugs (me-too status)

Name and address of API manufacturer.

Dy. No. and date of submission

Details of fee submitted

Proposed Pack size

Proposed unit price

wef 07-01-2016 specifying Tablet (General) section.

Antithrombotic agents, Direct Factor Xa inhibitors

As per Drug Pricing Committee (DPC)/SRO

Eliquis Tablet 2.5mg & 5mg (USFDA Approved)

Apiban Tablet 5mg of M/s Highnoon (Reg.No.

Glenmark Life Sciences Ltd, Plot 3109, GIDC, Industrial Estate, Ankleshwar, District Bharuch.

□ New Drug Product (NDP)⊠ Generic Drug Product (GDP)

☑ Domestic and Export sales

Dy.No 22727 dated 11-08-2022.

PKR 30,000/- DS No. 23409526937

Each Film Coated tablet contains:

□ Domestic sale□ Export sale

APLO 5mg Tablet

Apixaban...5mg

Film coated tablet

10's, 14's

104682)

Innovator's Specifications

	Module-II (Quality Over	all 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 Substar	ice:	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 (Conditions & duration of		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ 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 Equival Dissolution Profile	ence and Comparative	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 va product	llidation/verification of	Firm has submitted analytical method validation study reports for drug product.	
		STABILITY STU	UDY DATA	
Manufa	acturer of API	Glenmark Life Sciences District Bharuch.	Ltd, Plot 3109, GIDC, Industrial Estate, Ankleshwar,	
API Lo	ot No.	802008793		
_	otion of Pack iner closure system)	Alu-Alu Blister		
Stabilit	y Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time P	eriod	Real time: 6 months		

			Accelerated: 6 months			
Free	quency		Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mor			
Bato	ch No.		T-001	T-002	T-003	
Bato	ch Size		5000 Tablet	5000 Tablet	5000 Tablet	
Mar	nufacturing	Date	10-2021	10-2021	10-2021	
Date	e of Initiation	n	26-10-2021	26-10-2021	26-10-2021	
No.	of Batches			03		
	DOCU	MENTS / I	DATA TO BE PROVIDED A	LONG WITH STA	BILITY STUDY DATA	
1.			s approval of applications with f 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.					
5.			of HPLC software 21CFR & product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.		
6.	humidity		ta logger for temperature and g of stability chambers (real		midity monitoring of real time a	
Ren	narks of Ev	aluator ^{xxiii}	1			
	Sr.No.	Sections	Observations/Deficiencies/		Reply of applicant	
	1.	1.3.4	DML of drug product manufa 06-01-2021. Copy of valid DRAP shall be submitted.		Copy of valid DML No. 000333 renewed w.e.f. 07-01-2021 is submitted.	
	2.	1.6.5	manufacturer issued by con authority of country of origin as the submitted DML was va	a shall be submitted alid till 31-12-2023.	Copy of GMP certificate valid till 05/06/2025 is submitted.	
	3.	3.2.S.4.1	Specifications of drug substa different from those given substance in 3.2.S.4.4. Justify	in CoA of drug	Revised specifications submitted.	
	4.	3.2.S.4.4	CoA of drug substance g product manufacturer for 802008793 (Mfg 11-20, Exp submitted.	Batch Number	Submitted.	
	5.	3.2.S.7	Long term stability studies conducted at Zone IV-a conthe claimed shelf life shall be	ditions throughout	Submitted.	

6.	3.2.P.8	Documents for the procurement of API with	Submitted.	
		approval from DRAP shall be 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.

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 Potassium50mg
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).

		No.2, East Kangtai Road, Tangyin County, Anyang City, Henan Province, P. R. China. 456150.
Module-II (Quality Over	all 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 Substar	nce:	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 (Conditions & duration of		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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 48 months.
Module-III Drug Product	t:	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 va	alidation/verification of	Firm has submitted analytical method verification study reports for drug substance as well as drug product.
	STABILITY STU	UDY DATA
Manufacturer of API	_	narm Co., Ltd. No.2, East Kangtai Road, Tangyin enan Province, P. R. China. 456150.
API Lot No.	B#: 303210413-5	
Description of Pack	Alu-foil sachet	

(Con	tainer closur	e system)				
	lity Storage		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$	65% ± 6	5% D H	
Stabi	nty Storage	Condition		Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time	Period		Real time: 6 months Accelerated: 6 months			
Frequ	uency		Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mon			
Batcl	n No.		T-003	T-003 T-004 T-005		T-005
Batcl	n Size		1000 sachets.	1000	sachets.	1000 sachets.
Man	ıfacturing D	ate	04-2022	04-20	22	04-2022
Date	of Initiation		21-04-2022	21-04	-2022	21-04-2022
No. o	of Batches			1	03	
	DOCUM	ENTS / DA	TA TO BE PROVIDED A	LONG '	WITH STABILIT	Y STUDY DATA
1.			pproval of applications with ne firm (if any)	The firm	n has not submitted	any document.
2.			by concerned regulatory	HA201 Food a specifie for phan	90077) dated 06-1 and Drugs Admin	1-2021 issued by China istration. The certificate applies with Chinese GMFs.
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.		ments like chromatograms,	Firm h testing.		rtical record for product
5.			HPLC software 21CFR & oduct testing	for the		ate of 21 CFR compliance with audit trail report for
6.		nonitoring o	logger for temperature and of stability chambers (real	tempera		nonitoring of real time and
Rem	arks of Eva				T	
	Serial No.	Sections	Observations/Deficiend Short-comings	cies/	Reply of	applicant
	1.	3.2.P.8	Results/ supporting data time and accelerated s studies for six-month time shall be submitted.	tability	Submitted.	
•	propose the regis Manufa	cturer will j d shelf life a stration app cturer will	perform process validation	or six m	onths as per the co	ommitmentsubmitted in
309.	Name,		gistration application. Applicant / Marketing			ls , 15 Km Khurrianwala

Authorization Holder

Name, address of Manufacturing site.

3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan

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: Empagliflozin10mg
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

facturing Date of Initiation E Batches	04-2022 23-05-2022	04-2022 23-05-2022 03	04-2022 23-05-2022
facturing Data	04 2022	104 2022	04.2022
			2000 tablets.
			T-004
	Real Time: 0, 3, 6 (Mont	ths)	T 004
Accelerated: 6 months		onths)	
Period	Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Real time: 6 months	C/1/5% ± 5%RH	
ity Storage Condition			
iption of Pack	Alu-Alu blister		
ot No	•	Zone, Huaian, Jiangsu, Ch	ina.
facturer of API			
1	STABILITY STU	UDY DATA	
Analytical method validation/verification of product		Firm has submitted analystudy reports for drug	ytical method verification substance and analytical
Pharmaceutical Equiva Dissolution Profile	lence and Comparative	their product against the Diampa 10mg Tablet by M Firm has submitted CDF against the comparator p Tablet by M/s Getz F dissolution media (i.e. pH	M/s Getz Pharmaceuticals. Presults of their product roduct i.e. Diampa 10mg Pharmaceuticals in three I 1.2, pH 4.5, pH 6.8. The
Module-III Drug Produc	et:	Firm has submitted data its description, comp development, manufactur and control, process valid excipients, control of dru analytical procedures, v procedures, batch and specifications, reference s	of drug product including position, pharmaceutical re, manufacturing process ation protocols, control of ag product, specifications, rerification of analytical alysis, justification of tandard, container closure
		of drug substance at acconditions of Zone IV-A data is conducted at 40°C 12 months. The real time	\pm 2°C / 75% \pm 5% RH for stability data is conducted
		properties, solubility, phy specifications, analytical verification, batch analy specification, reference st	vsical form, manufacturer, I procedures and their vsis and justification of tandard, container closure
	Pharmaceutical Equiva Dissolution Profile Analytical method v product Analytical method v product facturer of API ot No. iption of Pack ainer closure system) ity Storage Condition Period ency No.	Analytical method validation/verification of product STABILITY STOP facturer of API M/s Jiangsu Yongan Phateconomic Development of No. 4500-202111001 Alu-Alu blister Real time: 30°C ± 2°C / Accelerated: 40°C ± 2°C / Accelerated: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Month No. T-002	properties, solubility, phy specifications, analytical verification, batch analy specification, reference stability Studies of Drug Substance (Conditions & duration of Stability studies) Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Firm has submitted stability of drug substance at a conditions of Zone IV-A data is conducted at 40°C 12 months. The real time at 30°C ± 2°C / 65% ± 5% to development, manufactur and control, process valid excipients, control of drug analytical procedures, approcedures, batch an specifications, reference system and stability studies. Pharmaceutical Equivalence and Comparative Dissolution Profile Pharmaceutical Equivalence and Comparative Dissolution Profile Firm has submitted phart their product against the Diampa 10mg Tablet by Norman Pharmaceutical Equivalence product Firm has submitted CDI against the comparator product Firm has submitted analytical method validation/verification Firm has submitted analytical method validation/verification Firm has submitted analytical method validation study reports for drug method va

		mmmarval of amplications resith	The firm	n has not submitted any decormant	
	•			n has not submitted any document.	
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		JS20209 Drug A the fin pharma	921) dated 21-09-2020 issued by Ji administration. The certificate specifierm complies with Chinese GMF ceutical products.	iangsu es that	
approval from DRAP (in case of import).		import	of 2kgs Empagliflozin cleared by AD		
*			as submitted analytical record for pr	roduct	
Compliance	e Record of	HPLC software 21CFR &	Firm ha	s submitted certificate of 21 CFR comp	liance
audit trail reports on product testing		for the	HPLC system along with audit trail repo		
		tempera	ature and humidity monitoring of real tin		
emarks of Evaluatorxxiii:					
Serial	Sections	Observations/Deficience	cies/	Reply of applicant	
No.		Short-comings		2 0 22	
1.	3.2.P.8	time and accelerated s	tability	Submitted.	
	Approval of manufactur authority of Documents approval from the approval from the audit trail results and according to the audit trail results and according to the audit trail results are arks of Evaluation No.	Approval of API/ DM manufacturer issued authority of country of authority of country of approval from DRAP (in the paper of the paper o	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. 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) arks of Evaluator in Sections Observations/Deficience Short-comings 1. 3.2.P.8 Results/ supporting data time and accelerated sections of the supporting data t	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. Compliance Record of HPLC software 21CFR & Firm has audit trail reports on product testing Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) arks of Evaluator xxxiii: Serial Sections Observations/Deficiencies/ No. Results/ supporting data of real time and accelerated stability	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Drug Administration. The certificate specificate firm complies with Chinese GMI pharmaceutical products. The certificate is valid till 20-09-2025. 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. 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 copy of commercial invoice import of 2kgs Empagliflozin cleared by AD DRAP, Lahore dated 07-12-2021. Firm has submitted analytical record for product testing. Firm has submitted certificate of 21 CFR comproduct testing. Firm has submitted certificate of 21 CFR comproduct testing. Firm has submitted certificate of 21 CFR comproduct testing. Firm has submitted certificate of 21 CFR comproduct testing. Firm has submitted record of digital data logger temperature and humidity monitoring of real time and accelerated) Firm has submitted certificate of 21 CFR comproduct testing. Firm has submitted record of digital data logger temperature and humidity monitoring of real time and accelerated) Firm has submitted record of digital data logger temperature and humidity monitoring of real time accelerated stability chambers. Firm has submitted certificate of 21 CFR comproduct testing. Firm has submitted record of digital data logger temperature and humidity monitoring of real time and accelerated) Firm has submitted analytical record of digital data logger temperature and humidity monitoring of real time and accelerated)

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.

shall be submitted.

• 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: Empagliflozin25mg
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 Ingelhei (USFDA approved).
For generic drugs (me-too status)	Diampa 25mg Tablet by Getz Pharmaceutica (Reg.No. 93074).
Name and address of API manufacturer.	M/s Jiangsu Yongan Pharmaceuticals Co. Ltd. Address: No. 18, 237 Provincial Road, Econom Development Zone, Huaian, Jiangsu, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-Fitemplate. Firm has summarized information related to nomenclature, structure, general properties solubility, physical form, manufacturers, description of manufacturing process and control specifications, analytical procedures and verification, batch analysis and justification 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 darelated to nomenclature, structure, gener properties, solubility, physical form, manufacture specifications, analytical procedures and the verification, batch analysis and justification specification, reference standard, container closus 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 batch of drug substance at accelerated and real tin conditions of Zone IV-A. The accelerated stabilidata is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 12 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutic

	Pharmaceutical Equival Dissolution Profile	lence and Comparative	excipients, control of dru analytical procedures, v procedures, batch and specifications, reference s system and stability studies Firm has submitted pharm their product against the Diampa 25mg Tablet by N Firm has submitted CDF against the comparator pro-	rerification of analytical alysis, justification of tandard, container closure es. maceutical equivalence of a comparator product i.e. M/s Getz Pharmaceuticals. Persults of their product roduct i.e. Diampa 25mg Pharmaceuticals in three [1.2, pH 4.5, pH 6.8. The
	Analytical method va	alidation/verification of	Firm has submitted analy	vtical method verification substance and analytical
		STABILITY ST	UDY DATA	
Manı	nfacturer of API		armaceuticals Co. Ltd. No. Zone, Huaian, Jiangsu, Ch	
API I	Lot No.	4500-202111001		
	cription of Pack ntainer closure system) Alu-Alu blister			
		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequ	nency	Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mon	•	
Batch	n No.	T-003	T-004	T-005
Batch	n Size	1500 tablets.	1500 tablets.	1500 tablets.
Manı	ıfacturing Date	04-2022	04-2022	04-2022
Date	of Initiation	09-05-2022	09-05-2022	09-05-2022
No. o	of Batches		03	
	DOCUMENTS / DATA	TO BE PROVIDED AI	LONG WITH STABILIT	Y STUDY DATA
1.	Reference of previous appr stability study data of the f		The firm has not submitted	any document.
2.	* *	concerned regulatory	Firm has submitted copy JS2020921) dated 21-09-Drug Administration. The the firm complies wipharmaceutical products. The certificate is valid till 2	2020 issued by Jiangsu certificate specifies that the Chinese GMP for
3.	Documents for the procapproval from DRAP (in case)		Firm has submitted copy of import of 2kgs Empagliflo DRAP, Lahore dated 07-12	ozin cleared by AD (I&E)
4.	. Data of stability batches will be supported by			

	_	Firm has submitted certificate of 21 CFR compliance
	audit trail reports on product testing	for the HPLC system along with audit trail report for
		product testing.
6.	December of Digital data language for temporature and	Firm has submitted record of digital data lagger for
0.	Record of Digital data logger for temperature and	Firm has submitted record of digital data logger for
		temperature and humidity monitoring of real time and

Remarks of Evaluator***:

Serial	Sections	Observations/Deficiencies/	Reply of applicant
No.		Short-comings	
1.	3.2.P.8	Results/ supporting data of real	Submitted.
		time and accelerated stability	
		studies for six-month time point	
		shall be 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: Apixaban2.5mg
	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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	•

	Analy		hod validation/verification of	of Firm has submitted study reports for dru	analytical method validation g product.
	STABILITY STUDY DATA				
		naceutical Co., Limited. No.18, 237 Provincial lopment Zone, Huaian, Jiangsu, China.			
API	Lot No.		APB-201909001		
	cription on tainer clo	f Pack osure syster	Alu-PVC Blister		
Stab	ility Stor	age Conditi	on Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$		
Time	e Period		Real time: 6 months Accelerated: 6 months		
Freq	uency		Accelerated: 0, 3, 6 (M Real Time: 0, 3, 6 (Mo		
Batc	h No.		2APPD01/21	2APPD02/21	2APPD03/21
Batc	h Size		9523 Tablet	9523 Tablet	9523 Tablet
Man	ufacturin	g Date	05-2021	05-2021	05-2021
Date	of Initia	tion	30-06-2021	30-06-2021	30-06-2021
No.	of Batche	es		03	
	DOC	UMENTS A	DATA TO BE PROVIDED A	ALONG WITH STAB	ILITY STUDY DATA
	Reference of previous approval of applications with stability study data of the firm (if any)		conducted for Vesoft Tablet, for which the inspection was conducted on 12-07-2018 and the report was presented in 284 th 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.		dated 07-12-2020		
3.	Documents for the procurement of API with approval from DRAP (in case of import).		cleared on 28-10-201	copy of commercial invoice 9 specifying import of 2.5Kg of ice is cleared by AD (I&E)	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		¥ **		
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)			ecord of digital data logger for dity monitoring of real time and hambers.	
Rem	Remarks of Evaluator***: Sr. Sections Observations/Deficiencies/ Sl. No.			hort-comings Rep	ply of applicant

1.	3.2.S.4	The Expiry date of drug substance given on	Typographical error.
		invoice is 08-21 whereas on CoA the expiry is	Revised CoA submitted
		05-2022. Clarification shall be submitted.	
2.	3.2.S.7	Long term stability studies data is submitted for	Submitted
		18 months. Stability studies data shall be	
		submitted for complete shelf life of the drug	
		substance.	

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.

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: Apixaban5mg
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)

I manufacturer	Jiangsu Yongan Pharmaceutical Co., Limited.
i manuracturer.	No.18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.
all 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.
ice:	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.
	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} \ / \ 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} \ / \ 65\% \pm 5\%$ RH for 36 months.
:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
ence and Comparative	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.
lidation/verification of	Firm has submitted analytical method validation study reports for drug product.
STABILITY STU	UDY DATA
Manufacturer of API Jiangsu Yongan Pharmaceutical Co., Limited. No.18, 237 Provinci Road, Economic Development Zone, Huaian, Jiangsu, China.	
APB-201909001	
Alu-PVC Blister	
	STABILITY STU Jiangsu Yongan Pharmac Road, Economic Develor APB-201909001

Stabi	ility Sto	rage Conditi		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time	e Period		Real time: 6 months Accelerated: 6 months			
Frequ	uency Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)					
Batc	h No.		5APPD01/21	5APPD02/21	5APPD03/21	
Batcl	h Size		5000 Tablet	5000 Tablet	5000 Tablet	
Man	ufacturi	ng Date	05-2021	05-2021	06-2021	
Date	of Initia	ation	30-06-2021	30-06-2021	30-06-2021	
No. o	of Batch	ies		03		
	DOC	CUMENTS	/ DATA TO BE PROVIDED A	LONG WITH ST	TABILITY STUDY DATA	
1.	Reference of previous approval of applications with stability study data of the firm (if any)		conducted for Ve was conducted or presented in 284 th report confirms f i. The HPI	pecific Inspection of the firmulation of the firmulation 12-07-2018 and the report the meeting of Registration Boar following points: LC software is 21CFR complies demonstrated audit trail reports.	pection ort was rd. The ant.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		10			
3.	Documents for the procurement of API with approval from DRAP (in case of import).		cleared on 28-10	0-2019 specifying import of 2. invoice is cleared by AD	5Kg of	
4.	attested	d respective	batches will be supported by documents like chromatograms, OA, summary data sheets etc.		ted analytical record for produ	ict
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing			ted certificate of 21 CFR compositem along with audit trail rep	•	
6.	humidi	•	data logger for temperature and ng of stability chambers (real ed)		tted record of digital data log humidity monitoring of real ti- lity chambers.	
Rem		Evaluatorx			T .	7
	Sr. No.	Sections	Observations/Deficiencies/ Sh	ort-comings	Reply of applicant	
	1.	3.2.S.4	The Expiry date of drug sub invoice is 08-21 whereas on C 05-2022. Clarification shall be	OA the expiry is	Typographical error. Revised CoA submitted	
	2.	3.2.S.7	Long term stability studies data 18 months. Stability studies submitted for complete shelf substance.	a is submitted for data shall be	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 M/s Wimits Pharmaceuticals Pvt. Limited, Plot No. **Authorization Holder** 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 ☐ 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 Each Vial Contains: Pharmaceutical ingredient (API) per unit 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** 1 x 1's Proposed Pack size 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 Weigida Pharmaceutical Co. Ltd. Address: Economic & Technological Development Zone, First Medical Zone, Datong Shanxi, China.

Module-II (Quality Overa	Il 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 Substand	ce:	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 (Conditions & duration of		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.
Module-III Drug Product:		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 Equivalent Dissolution Profile	ence and Comparative	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 ST	UDY DATA
• • • • • • • • • • • • • • • • • • • •		Pharmaceutical Co. Ltd. Economic & Technological Medical Zone, Datong Shanxi, China.
API Lot No.	F012104006 Manufacturi	ng date 04-2021, Expiry 03-2024
Description of Pack (Container closure system) 10mL Type 2 USP glass via reconstitution diluent (WFI).		s vial packed in unit carton provided with leaflet and FI).
Stability Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65^{\circ}$		

Time	Period	Real time: 6 months Accelerated: 6 months		
Frequency Accelerated: 0, 3, 6 (Mon Real Time: 0, 3, 6 (Month				
Batch	n No.	TCD001	TCD002	TCD003
Batch	n Size	500 vials	500 vials	500 vials
Manı	ıfacturing Date	07-2022	07-2022	07-2022
Date	of Initiation	18-07-2022	19-07-2022	20-07-2022
No. c	of Batches		03	
	DOCUMENTS / DAT	A TO BE PROVIDED	ALONG WITH STABIL	ITY STUDY DATA
1.	Reference of previous appr stability study data of the fi		h Not provided	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		y SX20180229 dated 06 Province Food and Dru	6-06-2018 issued by Shanxi ag Administration, China. The at the firm is operating at GMP compliance. GMP
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.			ytical record for product
5.	Compliance Record of HI audit trail reports on produc			ficate of 21 CFR compliance for ag with audit trail report for
6.	Record of Digital data log humidity monitoring of stal and accelerated)			ord of digital data logger for ty monitoring of real time and mbers.
314.	Name, address of Applic Authorization Holder	eant / Marketing	M/s Wimits Pharmace 129, Sunder Industrial	uticals Pvt. Limited, Plot No. l Estate Lahore.
	Name, address of Manufa	cturing site.	M/s Wimits Pharmace 129, Sunder Industrial I	uticals Pvt. Limited, Plot No. Estate Lahore.
	GMP status of the firm		☑ Manufacturer☐ Importer☐ Is involved in none of	of the above (contract giver)
				y of GMP certificate dated 08- pection conducted on 08-09-
	Evidence of approval of n	nanufacturing facility	DML/grant of section	opy of letter of renewal of dated 07-06-2022 specifying ection (Cephalosporin) section.
	Status of application		☐ New Drug Product (I ☐ Generic Drug Product	•

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 Cefuroxime750mg
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 10^{\circ}$

			5% RH for 36 months.	
	Module-III Drug Product		description, comp development, manufactor process control, process drug product, specific verification of analytic justification of specific	a of drug product including its position, pharmaceutical ure, manufacturing process and validation protocols, control of ations, analytical procedures, al procedures, batch analysis, cations, reference standard or sure system and stability.
	Pharmaceutical Equival Dissolution Profile	ence and Comparative	_	harmaceutical equivalence of e comparator's product Zinacef
	Analytical method v product	alidation/verification of	Firm has submitted a study report for drug pro	nalytical method verification oduct.
		STABILITY ST	TUDY DATA	
Manu	ufacturer of API		a Pharmaceutical Co. Ltd t Medical Zone, Datong S	1. Economic & Technological hanxi, China.
API I	Lot No.	F012104006 Manufactur	ring date 04-2021, Expiry	03-2024
Descr (Con	ription of Pack tainer closure system)	10mL Type 2 USP glast reconstitution diluent (W		rton provided with leaflet and
Stabi	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequ	nency	Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mon		
Batch	ı No.	TCG001	TCG002	TCG003
Batch	n Size	500 vials	500 vials	500 vials
Manu	ıfacturing Date	07-2022	07-2022	07-2022
Date	of Initiation	21-07-2022	22-07-2022	23-07-2022
No. c	of Batches		03	
	DOCUMENTS / DAT	A TO BE PROVIDED A	LONG WITH STABIL	ITY STUDY DATA
1.	Reference of previous appr stability study data of the fi		Not provided	
2.	* *		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).		Pharmaceuticals, Lahore 5Kg loan of Cefuroxime submitted copy of community 11-2021 specifying impact of the community of the	an letter from M/s Medisave e dated 02-07-2022 specifying s Sodium sterile. Firm has also mercial invoice cleared on 22- port of 30kg of Cefuroxime invoice is cleared by AD (I&E)

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
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 Cefuroxime1.5g
	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 Overa	ll 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 Substand	ce:	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 (Conditions & duration of		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.
Module-III Drug Product:		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 Equival Dissolution Profile	ence and Comparative	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 ST	UDY DATA
Manufacturer of API		Pharmaceutical Co. Ltd. Economic & Technological Medical Zone, Datong Shanxi, China.
API Lot No.	F012104006 Manufacturi	ing date 04-2021, Expiry 03-2024
Description of Pack (Container closure system)	l packed in unit carton provided with leaflet and FI).	
Stability Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 69$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 69$		

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		Date	07-2022	07-2022	07-2022		
Date	of Initiati	on	24-07-2022	25-07-2022	26-07-2022		
No.	of Batches	}		03			
	DOC	CUMENTS /	DATA TO BE PROVIDED	ALONG WITH ST	ABILITY STUDY DATA		
1.			approval of applications wit the firm (if any)	h 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)				numidity monitoring of real time and		
Rem	ark <u>s of E</u>	valuator ^{xxiii} :	T		,		
	Sr.	Section	Observations/shortcoming	s/deficiencies	Reply of applicant		
	03-0 rener		DML of M/s Wimits has be 03-02-2019. Receiving of a renewal from 2024 onward Licensing Division, DRAP s	pplication for DML ards submitted in	Application for DML renewal submitted in Licensing Division of DRAP dated 01-02-2024 is provided.		
	2. Valid GMP certificate of the manufacturer issued by the reauthority of the country of submitted.		relevant regulatory of origin shall be	Valid DML of API manufacturer (20160008) is submitted.			
	3. 2.S.6 & Label of drug substance s conditions as 2-8°C. Stability substance are conducted at fol Real time: 30°C ± 2°C / 65% Accelerated: 40°C ± 2°C / 75%		y studies of the drug ollowing condition: 0 ± 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.			

		T		
			However, the stability studies report concludes	Stability studies have
			that the "shelf life of Cefuroxime sodium is	been submitted
			three years if the product is preservedat 2-	accordingly as per Zone
			8°C". Clarify the storage conditions of the drug	Iva conditions.
			substance and submit stability studies data	
			accordingly.	
,	4. 3	3.2.P.2.2.1	• Details of innovator / reference/	Reference
		- 	comparator product including name and	product details:
			address of manufacturer and marketing	Zinacef Injection IM/IV
			authorization holder shall be submitted.	Manufcaturer: M/s GSK
			 Pharmaceutical equivalence of the applied 	Pakistan Ltd, Plot No. 5,
				Sector 21, Korangi
			drug shall be established with the innovator	Industrial Area, Karachi.
			/ reference/ comparator product and <i>results</i>	, , , , , , , , , , , , , , , , , , ,
			of all the quality tests (mentioned in USP	• Complete
			or section 3.2.P.5.1 of instant application)	pharmaceutical
			of the developed formulation and the	equivalence
			innovator / reference /comparator product	report submitted.
			shall be submitted and discussed.	
, [;	5. 3	3.2.P.2.6	Reference product manufacturer recommends	Conditions for in-use
			that "From a microbiological point of view once	stability were 2-8°C for
			opened, the product should be used	24 hours whereas it was
			immediately. If not used immediately in-use	inadvertently written as
			storage times and conditions prior to use are the	$30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm$
			responsibility of the user and would normally	5%RH.
			not be longer than 24 hours at 2-8°C when	
1			prepared in water for injections".	
			Applicant has conducted satisfactory in-use	
1			stability studies with sterile WFI at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$	
			$/65\% \pm 5\%$ RH. Justification shall be submitted	
1			regarding the in-use stability storage conditions.	
<u>L</u>			regulating the in use smothly storage conditions.	

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: Cephradine250mg (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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} \ / \ 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} \ / \ 65\% \pm 10^{\circ}$	

			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 Equival Dissolution Profile	lence and Comparativ	Firm has submitted pharmaceutical equivalence of their product against the comparator's product Velosef Injection. CDP is not applicable.	
	Analytical method validation/verification product		Firm has submitted ana report for drug product.	lytical method validation study
		STABILITY S	TUDY DATA	
Manufacturer of API		M/s NCPC Hebei Huam Address: 98 Hainan Shijiazhuang, Hebei, Ch	-	l. hnology Development Zone,
API I	Lot No.	B2172108010 Manufacturing date 08-2021, Expiry 07-2023		
	ription of Pack tainer closure system)	Glass vial packed in unit carton provided with leaflet and reconstitution diluent (WFI).		
Stabi	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch	ı No.	TJA001	TJA002	TJA003
Batch	n 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. c	f Batches	·	03	
	DOCUMENTS / DAT	A TO BE PROVIDED A	ALONG WITH STABIL	ITY STUDY DATA
1.	Reference of previous appr stability study data of the fi		Not provided	
2.			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.		
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: Cephradine500mg (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 Overa	Il 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 Substand	ce:	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 (Conditions & duration of		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.
Module-III Drug Product:		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 Equival Dissolution Profile	ence and Comparative	Firm has submitted pharmaceutical equivalence of their product against the comparator's product Velosef Injection. CDP is not applicable.
Analytical method vaproduct	alidation/verification of	Firm has submitted analytical method validation study report for drug product.
	STABILITY ST	UDY DATA
Manufacturer of API	M/s NCPC Hebei Huamin Address: 98 Hainan F Shijiazhuang, Hebei, Chi	
API Lot No.	B2172108010 Manufactu	ring date 08-2021, Expiry 07-2023
Description of Pack (Container closure system)	Glass vial packed in unit (WFI).	carton provided with leaflet and reconstitution diluent
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60^{\circ}$	5% ± 5%RH

		Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$	C / 75% ± 5%RH	
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequ	uency	Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mo	· · · · · · · · · · · · · · · · · · ·	
Batcl	n No.	TJB001	TJB002	TJB003
Batcl	n Size	500 vials	500 vials	500 vials
Manı	ufacturing Date	08-2022	08-2022	08-2022
Date	of Initiation	29-08-2022	30-08-2022	31-08-2022
No. o	of Batches		03	
	DOCUMENTS / DAT.	A TO BE PROVIDED	ALONG WITH STABIL	ITY STUDY DATA
1.	Reference of previous appr stability study data of the fir	* *	h Not provided	
2.	Approval of API/ DML/0 manufacturer issued by authority of country of original	concerned regulator	y HE20180086 dated 15- and Drug Administration that the firm is operatin compliance. GMP certi	opy of GMP Certificate No. 10-2018 issued by Hebei Food a, PRC. The certificate specifies g at satisfactory level of GMP ficate validity: 14/10/2023
3.	Documents for the procuren from DRAP (in case of imp		Pharmaceuticals, Lahore 5Kg loan of Cephradine has also submitted copy on 02-12-2021 specifically specificall	an letter from M/s Novamed e dated 10-08-2022 specifying with L-Arginine sterile. Firm of commercial invoice cleared fying import of 104kg of ginine sterile. The invoice is RAP, Lahore.
4.	Data of stability batches wil respective documents like of sheets, COA, summary data	hromatograms, Raw dat		ytical record for product
5.	Compliance Record of HI audit trail reports on produc			Ficate of 21 CFR compliance for ng with audit trail report for
6.	Record of Digital data log humidity monitoring of stat and accelerated)			ord of digital data logger for ty monitoring of real time and mbers.
318.	Name, address of Applic Authorization Holder	ant / Marketing	M/s Wimits Pharmace 129, Sunder Industria	euticals Pvt. Limited, Plot No. l Estate Lahore.
	Name, address of Manufa	cturing site.	M/s Wimits Pharmace 129, Sunder Industrial I	uticals Pvt. Limited, Plot No. Estate Lahore.
	Status of the applicant		☑ Manufacturer☐ Importer☐ Is involved in none of	of the above (contract giver)
	GMP status of the firm			y of GMP certificate dated 08- pection conducted on 08-09-
	Evidence of approval of n	nanufacturing facility	DML/grant of section	copy of letter of renewal of dated 07-06-2022 specifying ection (Cephalosporin) section.
	Status of application		☐ New Drug Product (I ☐ Generic Drug Product	

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: Cephradine1g (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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 10^{\circ}$

			5% RH for 36 months.	
	Module-III Drug Product		description, comp development, manufact process control, process drug product, specific verification of analytic justification of specific	a of drug product including its position, pharmaceutical ure, manufacturing process and validation protocols, control of ations, analytical procedures, al procedures, batch analysis, cations, reference standard or sure system and stability.
	Pharmaceutical Equival Dissolution Profile	ence and Comparativ		harmaceutical equivalence of e comparator's product Velosef
	Analytical method v product	alidation/verification o	Firm has submitted and report for drug product.	lytical method validation study
		STABILITY S	FUDY DATA	
	nfacturer of API	Address: 98 Hainan Shijiazhuang, Hebei, Ch	ina.	hnology Development Zone,
API I	Lot No.	B2172108010 Manufac	turing date 08-2021, Expir	ry 07-2023
	ription of Pack tainer closure system)	Glass vial packed in un (WFI).	it carton provided with le	aflet and reconstitution diluent
Stabi	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / \text{Accelerated}$: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / \text{C} / \text{Accelerated}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequ	iency	Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mor		
Batch	n No.	TJC001	TJC002	TJC003
Batch	n Size	500 vials	500 vials	500 vials
Manı	ıfacturing Date	09-2022	09-2022	09-2022
Date	of Initiation	01-09-2022	02-09-2022	03-09-2022
No. c	of Batches		03	
	DOCUMENTS / DAT	A TO BE PROVIDED	ALONG WITH STABIL	ITY STUDY DATA
1.	Reference of previous appropriate study data of the fi	* *	Not provided	
2.	Approval of API/ DML/omanufacturer issued by authority of country of orig	concerned regulatory	HE20180086 dated 15- and Drug Administration that the firm is operatin	opy of GMP Certificate No. 10-2018 issued by Hebei Food a, PRC. The certificate specifies g at satisfactory level of GMP ficate validity: 14/10/2023
3.	Documents for the procurer from DRAP (in case of imp		Pharmaceuticals, Lahoro 5Kg loan of Cephradine has also submitted copy on 02-12-2021 specifical specific control of the contro	an letter from M/s Novamed e dated 10-08-2022 specifying with L-Arginine sterile. Firm of commercial invoice cleared fying import of 104kg of ginine sterile. The invoice is RAP, Lahore.

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	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluatorxxiii:

Sr. No.	Section	Observations/shortcomings/deficiencies	Reply of applicant
1.		DML of M/s Wimits has been renewed w.e.f 03-02-	Application for DML renewal
		2019. Receiving of application for DML renewal from	submitted in Licensing
		2024 onwards submitted in Licensing Division, DRAP	Division of DRAP dated 01-
		shall be submitted.	02-2024 is provided.
2.	1.6.5	Valid GMP certificate of the drug substance	Submitted.
		manufacturer issued by the relevant regulatory	
		authority of the country of origin shall be submitted.	
3.	3.2.S.4.5,	CoA of drug substance states the storage conditions as	CoA of drug substance
	3.2.S.7,	not exceeding 10°C. Stability studies of the drug	provided in DMF is for China
	3.2.P.8	substance are conducted at following condition:	Zone II while CoA submitted
		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$	to applicant is as per Zone IVa
		Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$	that is why stability of drug
		Clarify the storage conditions of the drug substance and	substance is also submitted as
		submit stability studies data accordingly.	per Zone IVa conditions.
		• As the only processing done is filling, storage	Storage conditions of the drug
		conditions of the drug product shall also be	product is also as per Zone
		clarified and stability data of finished product	IVa.
		shall also be submitted accordingly.	
4.	1.5.6 &	Cefradine for Injection monograph is available in USP	Cephradine for injection is no
	3.2.S.4.5	and BP. CoA of drug substance states that the material	longer official in 2023 in
		complies with USP43. As the only processing done is	online USP so that is why we
		filling, justify your claim how the drug product	have claimed finished produc
		complies in-house specifications instead of USP.	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 Escitalopram1mg
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 clo studies of drug substance	sure system and stability
	Stability Studies of Dr (Conditions & duratio		drug substance at both ac conditions. The accelerate at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$	ity study data of 3 batches of celerated as well as real time ed stability data is conducted % RH for 6 months. The real ducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$
	Module-III Drug Prod	uct:	description, compo development, manufactu and process control, pr control of excipients, specifications, analytical analytical procedures, ba	are, manufacturing process rocess validation protocols, control of drug product, procedures, verification of extending the procedures of the process o
	Pharmaceutical Equi Dissolution Profile	valence and Comparative		irmaceutical equivalence of innovator's product Lexapro AbbVie.
	Analytical method product	validation/verification of	Firm has submitted and study reports for drug pro	alytical method verification oduct.
		STABILITY ST	UDY DATA	
Man	ufacturer of API		edimatla-Phase I & II Vill	4, 25 & 26, Phase-1, IDA, age Quthbullapur (Mandal), state, INDIA.
API	Lot No.	EO-091/22		
	ription of Pack tainer closure system)	Amber colored glass bottl	e with plastic cap and sea	1.
Stabi	llity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 7$		
Time	e Period	Real time: 6 months Accelerated: 3 months		
Freq	uency	Accelerated: 0, 3, 6 (Month Real Time: 0, 3, 6 (Months	•	
Batc	h No.	RD-GP-OS-PX-22013	RD-GP-OS-PX-22014	RD-GP-OS-PX-22015
Batc	h Size	20 bottles	20 bottles	20 bottles
Man	ufacturing Date	12-2022	12-2022	12-2022
Date	of Initiation	21-12-2022	21-12-2022	21-12-2022
No. o	of Batches		03	
	1	ATA TO BE PROVIDED A		TY STUDY DATA
1.	Reference of previous a stability study data of the	pproval of applications with e firm (if any)	Not submitted.	
2.		L/GMP certificate of API by concerned regulatory rigin.	05-2023 issued by Drug Government of Telangana	gs Control Administration, a, valid till 01-05-2024. The the firm is operating at

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.	•
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.		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.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
No. 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 <i>raw data</i> 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.
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- 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.

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		
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: Lacosamide10mg	
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 A	API manufacturer.	Venkata Narayana Active Ingredients Pvt. Ltd. Sy No. 69, Chandrapadiya Village, Vinjamur Mandal, Nellore District, Andhra Pradesh, India.
Module-II (Quality Ov	rerall 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 Subst	tance:	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 Dr (Conditions & duration		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 48 months.
Module-III Drug Produ	act:	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 Equi Dissolution Profile	valence and Comparative	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 product	validation/verification of	Firm has submitted analytical method verification study reports for drug product.
	STABILITY STU	JDY DATA
		ngredients Pvt. Ltd. Sy No. 69, Chandrapadiya Village, District, Andhra Pradesh, India.
API Lot No.	LC0670920	
Description of Pack (Container closure system)		ion filled in amber color glass bottle with plastic cap fied unit carton along with a leaflet insert
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\%$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$	
Time Period	Real time: 6 months	

			Accelerated: 3 months				
Free	quency			Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No. RD-GP-OS-CL-22016		RD-GP-OS-C	L-22017	RD-GP-OS-CL	-22018		
Bate	ch Size		20 Bottles	20 Bott	les	20 Bottle	es
Mar	nufactur	ing Date	12-2022	12-202	22	12-2022),
7			02-01-202	23			
No. of Batches 03							
	DO	OCUMENTS /	DATA TO BE PROVIDED A	LONG WITH ST	FABILITY	STUDY DATA	
1.			s approval of applications with the firm (if any)	for Capsules Deinspection was coreport was prese Board. The report	xstom 30m onducted on nted in 297 t confirms	ng & 60mg, for w n 21 & 22-07-2020 7 th meeting of Reg	hich the and the distration
2.	manut			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.	respec	tive documents	nes will be supported by attested s like chromatograms, Raw data ry data sheets etc.		ed analytic	al record for produ	ıct
5.	·		Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.				
6.	humidity monitoring of stability chambers (real time temperatur			humidity n	nonitoring of real		
Ren	narks of Sr	Evaluator Evaluator Sections	Observations/Deficiencies/ S	hort-comings	Renly of	applicant]
	No		Observations/Deficiencies/S	nor t-commigs	Kepiy oi	аррисані	
	1.		Evidence of availability of microbiology lab shall be sub		renewal conducted is submit stated the laborator	report of DML inspection d on 25-03-2022 ted wherein it is at microbiology with buffers quipment was	
	2. 3.2.S.4 API manufacturer has specifications. However, accept several tests given on CoA of		-	Revised	CoA claiming 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 HCl20mg
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 analysis and justification of standard, container closu studies of drug substance.	of specification, reference
	Stability Studies of Dru (Conditions & duration		Firm has submitted stability of drug substance at acceptability study data of 2 bar real time conditions. The acconducted at 40°C ± 2°C months. The real time stability of 20°C ± 2°C / 75% ± 5% RF	celerated conditions and the conditions of drug substance at accelerated stability data is $/75\% \pm 5\%$ RH for 6 willisty data is conducted at
	Module-III Drug Product:		Firm has submitted data of drug product including its description, composition, pharmaceutica 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 Compa 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 product	validation/verification of	Firm has submitted analy study reports for drug produ	
STABILITY ST			UDY DATA	
		Palam Pharma Pvt. Ltd, Plot No. 12/C, Phase –I, GIDC, Vatva, Ahmedabad, District Ahmedabad.		
API Lo	ot No.	FX/2111012		
	ption of Pack iner closure system)		filled in amber color glass b unit carton along with a leafl	
Stabili	ty Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\%$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0,1, 3, 6 (Mont 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	No. of Batches		03	
	DOCUMENTS / DATA TO BE PROVIDED A		ONG WITH STABILITY	STUDY DATA
	Reference of previous apstability study data of the	e 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.		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.	
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.		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.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
No.			
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 base20mg"	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 inhouse 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

322.	Name, address of Applicant / Marketing Authorization Holder	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A Sundar Industrial Estate, Raiwind Road Lahore. M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A Sundar Industrial Estate, Raiwind Road Lahore. ⊠ Manufacturer □ Importer □ Is involved in none of the above (contract giver)	
	Name, address of Manufacturing site.		
	Status of the applicant		
	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 Quetiapine20mg	
	Pharmacotherapeutic Group of (API)	Antipsychotics	
	Pharmaceutical form of applied drug	Oral liquid/suspension	
	Reference to Finished product specifications	USP Specifications	

	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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 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.
	Firm has submitted analytical method validation

Manufacturer of API		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	21QF0041			
Description of Pack (Container closure system)				White to off white oral succept and sealing packed in sealing packed				plastic
Stab	ility S	Stora	ge Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 7$				
Tim	e Peri	iod		Real time: 6 months Accelerated: 6 months				
Freq	uenc	у		Accelerated: 0, 3, 6 (Month Real Time: 0,1, 3, 6 (Month	·			
Bato	h No			RD-GP-OS-PQ-22019	RD-GP-OS-P	Q-22020	RD-GP-OS-PQ-	-22021
Batc	h Siz	e		20 Bottles	20 Bott	les	20 Bottles	S
Man	ufact	uring	g Date	12-2022	12-202	22	12-2022	
Date	of In	nitiat	ion	25-01-2023	25-01-20	023	25-01-202	.3
No.	of Ba	tche	S		03			
]	DOC	CUMENTS /	DATA TO BE PROVIDED A	LONG WITH ST	FABILITY	STUDY DATA	
1.	Reference of previous approval of applications wi stability study data of the firm (if any)				for Capsules Dexstom 30mg & 60mg, for which the inspection was conducted on 21 & 22-07-2020 and the report was presented in 297 th meeting of Registration Board. The report confirms the following: Firm has demonstrated audit trail reports of testing.			
2.	mar	nufac		OML/GMP certificate of API l by concerned regulatory f origin.	GMP &GLP/2	22073413	f GMP certificate valid till 03/0 Control Adminis	7/2024
3.			ents for the pro RAP (in case of		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.	resp	ectiv	ve documents	es will be supported by attested like chromatograms, Raw data y data sheets etc.		ed analytic	al record for produ	ct
5.					Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.			
6.	<u> </u>				Firm has submitted record of digital data logger fo temperature and humidity monitoring of real time and accelerated stability chambers.			
Ren	_		valuator ^{xxiii} :					
		Sr. No.	Sections	Observations/Deficiencies/ S	hort-comings	Reply of	applicant	
1. Evidence of availability of microbiology lab shall be sub			renewal conducted is submit stated th	report of DML inspection d on 25-03-2022 ted wherein it is at microbiology with buffers				

			and equipment was
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 Quetiapine20mg"	present. It is a typographical error. Applicant has changed label claim according to reference product. Full fee of registration shall be submitted as prescribed for preregistration variation (correction of composition as per reference regulatory authority's
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 preregistration 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. 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.	· · · · · · · · · · · · · · · · · · ·
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 of the second of the	"batch release data at initial time point" of r sufficient enough to perform complete stability	six months as per the commitment submitted in		
	Authorization Holder	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: Atomoxetine4mg		

Psychoanaleptics,

sympathomimetics

100mL

As per SRO

Not available.

Transparent Oral liquid/solution

STRATTERA 4mg / mL (MHRA Approved)

Innovator's Specifications

Pharmacotherapeutic Group of (API)

Pharmaceutical form of applied drug

For generic drugs (me-too status)

Proposed Pack size

Proposed unit price

Reference to Finished product specifications

The status in reference regulatory authorities

acting

Centrally

Name and address of A	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 Ov	erall 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 Subst	ance:	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 Dru (Conditions & duration		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 12 months.
Module-III Drug Produ	ict:	Firm has submitted data of drug product including 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 Equiv Dissolution Profile	valence and Comparative	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 STU	UDY DATA
Manufacturer of API		l, Plot No. IP No. 27-29, Parts of Sy Nos: 18, 273, 274 area, I Phase, Kudumalakunte village, Gowribidanur strict, India.
API Lot No.	ATM/007	
Description of Pack Clear transparent clear of		solution filled in amber color glass bottle with plastic

(Container closure system) cap and sealing packed in specified unit carton along with				th 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				The state of the s	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batc	h No	Э.		RD-GP-OS-AT-22007	RD-GP-OS	-AT-22008	RD-GP-OS-AT	-22009
Batc	h Si	ze		20 Bottles	20 Bo	ottles	20 Bottles	s
Man	ufac	turing	Date	09-2022	09-2	2022	09-2022	
Date	of I	nitiatio	on	21-10-2022	28-10	-2022	28-10-202	2
No.	of B	atches			03			
		DOC	UMENTS / D	ATA TO BE PROVIDED A	LONG 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 297 th meeting of Registration Board. The report confirms the following: Firm has demonstrated audit trail reports of testing.				
2.				by concerned regulatory	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.			nts for the proc AP (in case of	urement of API with approval 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.	res	pectiv	e documents li	s will be supported by attested ke chromatograms, Raw data data sheets etc.		nitted analytic	al record for produ	ct
5.		•	nce Record of l reports on pro		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)				nd humidity m	nonitoring of real t		
Rem	Remarks of Evaluator ^{xxiii} :			Chaut	Donly of on	mliaant		
			Observations/Deficiencies/comings	Short-	Reply of ap	ррпсан		
		1.	1.4.1	Applicant has applied as go whereas the applied formular already registered by DRAP available). However, same approved in 324th meeting of Board and registration lett issued. Differential fee (Rs New Drug Product (if application of issuance of registration 1 submitted.	lation is not (me-too is not e product is of Registration er is not yet s. 45,000) for able at the time	differential	has submitted fee of Rs. 45000 25365918873) is	

r				
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 Atomoxetine4mg"	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 preregistration fee.	
3.	3.2.S.7	Long term stability studies data for API is submitted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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 inhouse 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: Risperidone1mg
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 Dr (Conditions & duration		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 48 months.		
	Module-III Drug Prod	uct:	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 Equi Dissolution Profile	valence and Comparative	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 product	validation/verification of	Firm has submitted analytical method verification study reports for drug product.		
		STABILITY ST	UDY DATA		
Manı	nfacturer of API	Venkata Narayana Active In Sy No. 69, Chandrapadiya Pradesh, India.	ngredients Pvt. Ltd. Village, Vinjamur Mandal,	Nellore District, Andhra	
API l	Lot No.	RN0030321			
	ription of Pack tainer 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			
Stabi	lity Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	nency	Accelerated: 0, 1, 3, 6 (Mor Real Time: 0, 3, 6 (Months)			
Batch	n No.	RD-GP-OS-VP-22004	RD-GP-OS-VP-22005	RD-GP-OS-VP-22006	
Batch	n Size	20 Bottles	20 Bottles	20 Bottles	
Manu	ufacturing Date	09-2022	09-2022	09-2022	
Date	of Initiation	18-10-2022	18-10-2022	18-10-2022	
No. c	of Batches		03		
	DOCUMENTS / DA	TA TO BE PROVIDED AI	LONG WITH STABILITY	STUDY DATA	
1.	Reference of previous apstability study data of the		Product Specific Inspection for Capsules Dexstom 30m inspection was conducted or report was presented in 297 Board. The report confirms Firm has demonstrated audit	g & 60mg, for which the n 21 & 22-07-2020 and the 1th meeting of Registration the following:	

2.	**	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.	· · · · · · · · · · · · · · · · · · ·
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 Evaluatorxxiii:

Sr.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
No.			
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 $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 48 months. Real time stability studies data and report shall be submitted as per Zone Iva conditions i.e $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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: Isotretinoin40mg
	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-III 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, 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.	
		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 Dru (Conditions & duration	•	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 48 months.	
Module-III Drug Produ	ict:	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 Equiv Dissolution Profile	valence and Comparative	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 product	validation/verification of	Firm has submitted analytical method verification study reports for drug product.	
STABILITY ST		UDY DATA	
Manufacturer of API M/s Horster Biotek Pvt Ltd RD Industrial Area Indore -		Khasra No. 259, Plot No. 1&2, Sukhliya Sanwer 452015(India).	
API Lot No. HBPL/ISO/22-23/007			
Description of Pack (Container closure system) Alu-Alu Blister			
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\%$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75$		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency Accelerated: 0, 1, 3 (Month Real Time: 0, 3 (Months)		as)	

Bate	ch No).		073NS01	073N	IS02	073NS03
Bate	ch Siz	ze		2000 capsules	2000 capsules		2000 capsules
Maı	nufac	turing	Date	04-2023	04-2	023	04-2023
Dat	e of I	nitiati	on	20-04-2023	20-04	-2023	20-04-2023
No.	of Ba	atches			03		
		DOC	UMENTS / D	ATA TO BE PROVIDED A	LONG 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 u	nit of API manufacturer.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).			05-04-2023 s	pecifying 1k	clearance certificate date g of Isotretinoin. Th &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.		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)			nd humidity m	of digital data logger for onitoring of real time and rs.		
Ren	narks	s of E	valuator ^{xxiii} :		•		
		Sr.	Sections	Observations/Deficiencies/	Short-	Reply of ap	plicant
	_	No	2.3.S.4.4 & 3.2.S.4.4	comings CoAs of three batches of AP i.e. 2009065, IST-20230706 Chongqing Huapont Pharm HBPL/ISO/22-23/007 (g Horster Biotek). Clarifica submitted regarding the m drug substance along with following: CoA (from manuapplicant) of the l substance used manufacturing of sta Approval of API certificate of API issued by concern authority of country	i (generated by Co. Ltd) and enerated by tion shall be anufacturer of submission of ufacturer and batch of drug in the ability batches. DML/GMP manufacturer and regulatory	manufacturing batches is 23/007 manufacture Bit Khasra No. 1&2, Sukhling RD Industria 452015(Indiananufacture are subnmitted Approval DML/GMP	al Area Indore – a). CoAs (from r and applicant) ed. of API/ certificate of site of API r issued by regulatory
		2.	3.2.P.8	Results and raw data of accelerated stability studies shall be submitted for 6 point	dies of FPP	Submitted.	

	3.	3.2.P.8	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	
D ' D C 1 C 1 ' C PIDMI/CMD //C / Cl 1 / C / C 11				

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: -

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 Cefoperazone1gm 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	
	1's	
Proposed Pack size	1 8	

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. 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- template. Firm has summarized information rela to nomenclature, structure, general properti solubilities, physical form, manufacture description of manufacturing process and control specifications, analytical procedures and validation, batch analysis and justification specification, reference standard, container clos system and stability studies of drug substance a drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance description of manufacture, solubilities, physical for manufacturers, description of manufacturers, and controls, specifications, analytic procedures and its validation, batch analysis a justification of specification, reference standary container closure system and stability studies drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batch of drug substance at both accelerated as well as retime conditions. The accelerated stability data conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for months. The real time stability data is conducted $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months.
Module-III Drug Product:	Firm has submitted data of drug product includits description, composition, pharmaceutidevelopment, manufacture, manufacturing procand process control, process validation protococontrol of excipients, control of drug produspecifications, analytical procedures, validation analytical procedures, batch analysis, justification specifications, reference standard or materia container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence their product against the innovator's product Cel 2 g manufactured by Bosch Pharmaceuticals I Ltd.
Analytical method validation/verification of product	Firm has submitted analytical method validat study reports for drug substance as well as dr

			product.	
	STABILITY ST			
Manufacturer of API (Cefoperazone Sodiu Lucent drugs Pvt Ltd Factory: Sy. No. 10, 0 Reddy (Dist.)Telanga		l Gaddapotharam Village, Jii	nnaram Mandal, sanga	
API Lot No.		CS/32/15, CS/35/15,	CS/38/15	
API Lot No.		13072016, 15072016	5, 18072016	
Description of Pack (Container closure syst	em)	Vial		
Stability Storage Condi	tion	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time Period		Real time: 6 months Accelerated: 6 month	ns	
Frequency		Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (M		
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 o	f Manufactu	ring site.	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E. Super Highway Karachi	
Status of the app	Status of the applicant GMP status of the firm		 ☑ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver) 	
GMP status of th			Firm has submitted copy of GMP certificate dated 24/02/2022 based on inspection conducted on 10-01-2022.	
Evidence of appr	Evidence of approval of manufacturing facility		Firm has submitted copy of dated 29-04-2022 specify Cephalosporin (New)	
Status of applica	Status of application		☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)	
Intended use of p	Intended use of pharmaceutical product		□ Domestic sale□ Export sale⊠ Domestic and Export sales	
Dy. No. and date submitted	of submissi	ion & Details of fee	Dy.No 20821 dated 23-08 Rs.30,000/- dated 16-09-2	-2023
The proposed pro	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 t Cefoperazone500mg Sulbactam Sodium Equivalent t Sulbactam500mg
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-P template. Firm has summarized information related to nomenclature, structure, general properties solubilities, physical form, manufacturer description of manufacturing process and control specifications, analytical procedures and invalidation, batch analysis and justification 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 darelated 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 batch of drug substance at both accelerated as well as retime conditions. The accelerated stability data conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for months. The real time stability data is conducted $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months.

	Pharmaceutical Equivalence and Comparative Dissolution Profile		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
			Firm has submitted pharmaceutical equivalence of their product against the innovator's product Cebac 1 g manufactured by Bosch Pharmaceuticals Pvt. Ltd.	
	Analytical method valid product	lation/verification of	Firm has submitted anal study reports for drug su product.	
		STABILITY ST	UDY DATA	
Manu	Manufacturer of API (Cefoperazone Sod Lucent drugs Pvt Lt Factory: Sy. No. 10 Reddy (Dist.)Telans		l Gaddapotharam Village, Jinnaram Mandal, sanga	
API L	ot No.	CS/32/15, CS/35/15,	CS/38/15	
Hubei Hongyuan pl 428 Yishui North			armaceutical Technology Road Fengshan Town Luotian County Huanggang,	
API L	ot No.	13072016, 15072016	, 18072016	
	Description of Pack (Container closure system)			
Stabil	ity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$		
Time	Period	Real time: 6 months Accelerated: 6 month	.s	
Frequ	equency Accelerated: 0, 3, 6 Real Time: 0, 3, 6 (1)		-	
Batch	No.	IB-101	IB-103	IB-105
Batch	Size	500 Vials	500 Vials	500 Vials
Manu	facturing Date	02-2022	02-2022	02-2022
Date of	of Initiation	02-02-2022	03-02-2022	04-02-2022
No. of	No. of Batches		03	
	DOCUMENTS / DATA TO BE PROVIDED A		LONG WITH STABILIT	Y STUDY DATA
1.	Reference of previous approval of applications w stability study data of the firm (if any)		th N/A	
2.	Approval of API/ DML/GMP certificate of a manufacturer issued by concerned regulat authority of country of origin.		ry GMP Certificate (No. 7' 2020 issued by Drug Govt of Telangana). Th	y of Lucent Drugs pvt Ltd 774/E1/2020 dated 29-01- Control Administration e certificate specifies that satisfactory level of GMP

		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.	
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)	

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 Cefoperazone1g Sulbactam Sodium Equivalent to Sulpactam500mg
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.
	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.

	(Conditions & duration of	Stability studies)	time conditions. The a conducted at $40^{\circ}\text{C} \pm 2$	oth accelerated as well as real accelerated stability data is 2° C / 75% \pm 5% RH for 6 stability data is conducted at % RH for 24 months.	
Module-III Drug Product:			its description, compo development, manufact and process control, p control of excipients, specifications, analytic analytical procedures,	cture, manufacturing process rocess validation protocols, control of drug product, cal procedures, validation of batch analysis, justification rence standard or materials,	
	Pharmaceutical Equivalent Dissolution Profile	ce and Comparative	their product against t	narmaceutical equivalence of he innovator's product Cebac Bosch Pharmaceuticals pvt	
			Comparative Dissolution Profile: N/A.		
	Analytical method validat product	ion/verification of	Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
STA	BILITY STUDY DATA				
Manı	ufacturer of API	(Cefoperazone Soc Lucent drugs Pvt L Factory: Sy. No. 10 Reddy (Dist.)Telan	td , Gaddapotharam Village	e, Jinnaram Mandal, sanga	
API I	Lot No.	CS/32/15, CS/35/1	35/15, CS/38/15		
Manı	ufacturer of API	(Sulbactam Sodium) Hubei Hongyuan pharmaceutical Technology 428 Yishui North Road Fengshan Town Luotian County Huanggang, 438600 China			
API I	Lot No.	13072016, 1507201	16, 18072016		
l	ription of Pack tainer closure system)	Vial	Vial		
Stabi	lity Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time	Period		Real time: 6 months Accelerated: 6 months		
Frequ	Frequency Accelerated: 0, 3, Real Time: 0, 3, 6				
Batch	ı No.	IB-125	IB-127	IB-129	
Batch	n Size	500 Vials	500 Vials	500 Vials	
Manu	ıfacturing Date	02-2022	02-2022	02-2022	
Date	of Initiation	22-02-2022	23-02-2022	24-02-2022	
No. of Batches 03		03	•	•	

DOCU	OCUMENTS / DATA 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 chromatogram Raw data sheets, COA, summary data sheets etc.				
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.			
Remai	rks of Evaluator:	•			
•	were adopted by the Registration Board in its 27	already approved by DRAP (generic/me-too status) name of firm.			
Decision	on: Registration Board deferred the case for su	bmission 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 Cefoperazone500mg
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

	Module-III Drug Product: I Dissolution Profile I Dissolution Profile I Dissolution Profile		months. The real tim	± 2°C / 75% ± 5% RH for 6 he stability data is conducted at 5% RH for 24 months.	
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
				pharmaceutical equivalence of the innovator's product Cefobid by Pfizer.	
			Comparative Dissolu	tion Profile: N/A.	
	Analytical method validation/verific product			analytical method validation ug substance as well as drug	
		STABILITY S	TUDY DATA		
Manu	facturer of API				
		Lucent drugs Pvt Ltd Factory: Sy. No. 10, Gaddapotharam Village, Jinnaram Mandal, sanga Reddy (Dist.)Telanga-502325- India			
API I	Lot No.	CS/32/15, CS/35/15,	CS/38/15		
	ription of Pack rainer closure system)	Vial			
Stabil	lity Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	nency	Accelerated: 0, 3, 6 (Me Real Time: 0, 3, 6 (Me	The state of the s		
Batch	No.	IB-76	IB-77	IB-79	
Batch	Size	500 Vials	500 Vials	500 Vials	
Manu	facturing Date	02-2022	02-2022	02-2022	
Date	of Initiation	18-02-2022	21-02-2022	23-02-2022	
No. o	No. of Batches		03		
	DOCUMENTS / DATA TO BE PROVIDED A		ALONG WITH STAP	BILITY STUDY DATA	
1.	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	copy of Lucent Drugs pvt Ltd b. 7774/E1/2020 dated 29-01- Control Administration Govt of		

3.		Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.			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.
Re	ma	rks of Evaluator:	
	Sr No		Firm's response
	1.		
	2.	21CFR & audit trail reports on product testing shall be submitted.	
	J.	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.	
De	cisi	ion: Registration Board deferred the case for ${f s}$	ubmission of reply to the above cited shortcomings.
33	0.	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)
Ì		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 Cefoperazone1g
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 24 months.
Module-III Drug Product:	Firm has submitted data of drug product including its

			development, manufand process control control of excipien specifications, analy analytical procedures	mposition, pharmaceutical facture, manufacturing process, process validation protocols, its, control of drug product, tical procedures, validation of s, batch analysis, justification of tence standard or materials, item and stability.	
	Pharmaceutical Equiva Dissolution Profile	alence and Comparative	their product agai Viperazone 1g manu	pharmaceutical equivalence of nst the innovator's product factured by Kalmia Health Care	
	Analytical method va	alidation/verification of		analytical method validation rug substance as well as drug	
	p230000		product.	and succession as well as along	
		STABILITY S	STUDY DATA		
Man	ufacturer of API	Lucent drugs Pvt Ltd Factory: Sy. No. 10, Gaddapotharam Village, Jinnaram Mandal, sanga Reddy (Dist.) Telanga-502325- India		Jinnaram Mandal, sanga	
API	Lot No.	CS/32/15, CS/35/15, C	CS/32/15, CS/35/15, CS/38/15		
	cription of Pack stainer closure system)	Vial			
Stab	ility Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time	e Period	Real time: 6 months Accelerated: 6 months			
Freq	uency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batc	h No.	IB-69	IB-72	IB-75	
Batc	h Size	500 Vials	500 Vials	500 Vials	
Man	ufacturing Date	02-2022	02-2022	02-2022	
Date	of Initiation	12-02-2022	14-02-2022	16-02-2022	
No.	of Batches		03		
	DOCUMENTS / DAT	A TO BE PROVIDED	ALONG WITH STA	BILITY STUDY DATA	
1.	Reference of previous a with stability study data		N/A		
2. Approval of API/ DML/C manufacturer issued by authority of country of or		concerned regulatory	GMP Certificate (No. issued by Drug Co Telangana). The certificate (No. issued by Drug Co	copy of Lucent Drugs pvt Ltd 7774/E1/2020 dated 29-01-2020 ntrol Administration Govt of ficate specifies that the firm is ry level of GMP compliance.	
3.	Documents for the pro approval from DRAP (in		Not submitted.		
4.	4. Data of stability batches will be supported by		testing.	nalytical record for product	

5.		ompliance Record of HPLC software 21CFR & adit 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.	hι		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Re	mar	ks 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. 5. 	Compete batch manufacturing record for three stability batches shall be submitted. Documents confirming procurement of drug	
		substance.	
De	cisio	on: Registration Board deferred the case for s	ubmission of reply to the above cited shortcomings
33	1.	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		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 Cefotaxime500mg
		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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 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.

	Dissolution Profile th		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				analytical method validation ug substance as well as drug
	•	STABILITY	ST	UDY DATA	
Manı	ufacturer of API	Harbin Hejia Pharmaceutical Co., Ltd Economic & Technical Development Zone Shanghzhi City Heilongjiang- China			
API I	Lot No.	SN202004002, SN20)20	004003. SN202004004	
	ription of Pack tainer closure system)	Vial			
Stabi	lity Storage Condition	Real time: 30°C ± 2°C Accelerated: 40°C ± 2			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	uency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch	ı No.	CF-135		CF-137	CF-139
Batch	n Size	500 Vials		500 Vials	500 Vials
Manu	ufacturing Date	02-2022		02-2022	02-2022
Date	of Initiation	01-02-2022		03-02-2022 05-02-2022	
No. c	of Batches			03	
	DOCUMENTS / DATA	TO BE PROVIDED	A	LONG WITH STAB	ILITY STUDY DATA
1.	Reference of previous as with stability study data of		ıs .	N/A	
2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		y	HL2022004) dated (Food & Drugs Ad		
3.	3. Documents for the procurement of API with approval from DRAP (in case of import).		h	Not submitted.	
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		e	Firm has submitted an testing.	alytical record for product	
5.	•				rtificate of 21 CFR compliance along with audit trail report for
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real to			ecord of digital data logger for dity monitoring of real time and nambers.	

Rema	marks of Evaluator:			
Sr	Observations	Firm's response		
No.				
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.			
Decisi	on: Registration Board deferred the case for	submission of reply to the above cited shortcomings		
332.	Name, address of Applicant / Marketing	M/s Mission Pharmaceuticals Plot # A-94, S.I.T.E.		
332.	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			
	Givir status of the fifth	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			
	Evidence of approval of manufacturing facility	dated 29-04-2022 specifying Dry Powder Injection		
		Cephalosporin (New)		
	Charles of a military and	* * *		
	Status of application	□ New Drug Product (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	Dy.No 20843 dated 23-08-2023		
	fee submitted	Rs.30,000/- dated 16-09-2022		
	Tee saonnaea	13.50,000/- uaicu 10-07-2022		
	The proposed proprietary name / brand name	Ceftox 1g Injection		
	Strength / concentration of drug of Active	Each Vial contains:		
	Pharmaceutical ingredient (API) per unit	Cefotaxime Sodium Equivalent to		
		Cefotaxime1g		
	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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} \ / \ 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} \ / \ 65\% \pm 5\%$ RH for 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		
Man	ufacturer of API	Harbin Hejia Pharm Economic & Techr China		Shanghzhi City Heilongjiang-	
API	API Lot No. SN202004002, SN202004003. SN202004004				
	cription of Pack ntainer closure system)	Vial			
Stab	ility Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm$			
Time	e Period	Real time: 6 months Accelerated: 6 mont			
Freq	uency	Accelerated: 0, 3, 6 Real Time: 0, 3, 6 (N			
Batc	h No.	CF-141	CF-143	CF-145	
Batc	h Size	500 Vials	500 Vials	500 Vials	
Man	ufacturing 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	A TO BE PROVIDE	D ALONG WITH STAI	BILITY STUDY DATA	
1.	Reference of previous a with stability study data of		ns N/A		
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		ry HL2022004) dated 04 & Drugs Administrati	& Drugs Administration. The certificate specifies that the firm is operating at satisfactory level of GMP	
3.	Documents for the procapproval from DRAP (in		th Not submitted.		
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		ke testing.	nalytical record for product		
5.				ertificate of 21 CFR compliance along with audit trail report for	
6.	Record of Digital data log humidity monitoring of time and accelerated)		al temperature and humi		

Rema	rks 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. 5.	Compete batch manufacturing record for three stability batches shall be submitted. Documents confirming procurement of drug	
	substance.	
Decisi	on: 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 facilit	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 t 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 Cefepime2gm
	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	l's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	1	f.

For generic drugs (me-to-	o status)	Cefstar 2gm Injection of M/s, Barrette Hodgson (Reg.No. 089284)	
Name and address of AP	I manufacturer.	Akum Life Sciences Limited	
		Unit I : VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)	
Module-II (Quality Overa	all 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 Substan	ace:	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 (Conditions & duration o		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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 Equival Dissolution Profile	ence and Comparative	Firm has submitted pharmaceutical equivalence of their product against the reference product	
Analytical method va		Firm has submitted analytical method validation study reports for drug substance as well as drug product.	
	STABILITY STU	DY DATA	
Manufacturer of API	Akum Life Sciences Lim Unit I: VIII, Sundran, F Punjab-140 201 (India)	nited P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali,	
API Lot No.	CPM/017/15, CPM/019/	15, CPM/021/15	
•			

	ption of Pack iner closure system)	Vial			
Stability Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / \text{Accelerated: } 40^{\circ}\text{C} \pm 2^{\circ}\text{C}$					
		Real time: 6 months Accelerated: 6 month			
Freque	ency	· ·	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	
Manuf	Cacturing Date	02-2022	02-2022	02-2022	
No. of	Batches		03		
334.	Name, address of Appl Authorization Holder	icant / Marketing	M/s Mission Pharm S.I.T.E. Super Highw	naceuticals Plot # A-94, way Karachi	
	Name, address of Manut	Cacturing site.	M/s Mission Pharm S.I.T.E. Super Highwa	aceuticals Plot # A-94, ay Karachi	
	Status of the applicant		☑ Manufacturer☐ Importer☐ Is involved in no giver)	 ✓ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract 	
	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		section dated 29-04-20	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 ☐ Generic Drug Product		
	Dy. No. and date of submission & Details of fee submitted		e Dy.No 20836 dated 23 Rs.30,000/- dated 16-0		
	The proposed proprietary name / brand name		Misapime 1gm Inject	tion	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each Vial contains: Cefepime Hydroch Cefepime1gm	lloride Equivalent to	
	Pharmacotherapeutic Group of (API)		Cephalosporin Antibiotics		
	Pharmaceutical form of applied drug		y powder for injection	n	
	Reference to Finished product specifications		(USP Specification)	(USP Specification)	
	Proposed Pack size	_	1's		
	Proposed unit price		As per SRO		
	The status in reference re	egulatory authorities	USFDA Approved		
	For generic drugs (me-too status)		Cefstar 1gm Injection (Reg.No. 030954)	Cefstar 1gm Injection of M/s, Barrette Hodgson (Reg.No. 030954)	
	Name and address of API manufacturer.		Akum Life Sciences L	imited	

		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 Su (Conditions & duration of S		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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 Equivalent Dissolution Profile	ce and Comparative	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Cefstar 1gm manufactured by Barrett Hodgson Pakistan Pvt Ltd.
Analytical method valid product	dation/verification of	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
	STABILITY STUI	DY DATA
U	kum Life Sciences Lim Init I : VIII, Sundran, P unjab-140 201 (India)	ited .O. Mubarakrpur, Tehsil Derabassi, Distt Mohali,
API Lot No.	PM/017/15, CPM/019/	15, CPM/021/15
Description of Pack V	'ial	

(Conta	iner closure system)				
Stability Storage Condition Real time: $30^{\circ}C \pm 2^{\circ}C$ / Accelerated: $40^{\circ}C \pm 2^{\circ}C$					
Time Period Real time: 6 months Accelerated: 6 month		s			
Freque	ency		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	
Manuf	acturing Date	02-2022	02-2022	02-2022	
No. of	Batches		03		
335.	Name, address of Appl Authorization Holder	icant / Marketing	M/s Mission Pharm S.I.T.E. Super Highw	naceuticals Plot # A-94, vay Karachi	
	Name, address of Manuf	Cacturing site.	M/s Mission Pharm S.I.T.E. Super Highwa	aceuticals Plot # A-94, ny Karachi	
	Status of the applicant		☑ Manufacturer☐ Importer☐ Is involved in not giver)	 ✓ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract) 	
	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		section dated 29-04-20	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 ☐ Generic Drug Produ		
	Dy. No. and date of submission & Details of fee submitted		Dy.No 20835 dated 23 Rs.30,000/- dated 16-0		
	The proposed proprietary name / brand name		Misapime 500mg Inj	ection	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each Vial contains: Cefepime Hydroch Cefepime500m		
	Pharmacotherapeutic Group of (API)		Cephalosporin Antibiotics		
	Pharmaceutical form of applied drug		y powder for injection	า	
	Reference to Finished product specifications		(USP Specification)	(USP Specification)	
	Proposed Pack size		1's	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-to	oo status)	Cefstar 500mg Inje Hodgson (Reg.No. 030		

Name and address of API	manufacturer.	Akum Life Sciences Limited
Traine and address of the	manufactor or .	
		Unit I: VIII, Sundran, P.O. Mubarakrpur, Tehsil Derabassi, Distt Mohali, Punjab-140 201 (India)
Module-II (Quality Overal	Il 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	re:	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 S (Conditions & duration of		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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 Equivale Dissolution Profile	nce and Comparative	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 val	idation/verification of	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
	STABILITY STUI	DY DATA
	Akum Life Sciences Lim Unit I : VIII, Sundran, P Punjab-140 201 (India)	ited .O. Mubarakrpur, Tehsil Derabassi, Distt Mohali,

API	Lot No.	CPM/017/15, CPM/019/15, CPM/021/15		
	ription of Pack tainer closure system)	Vial		
Stabi	ability Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time	e Period	Real time: 6 months Accelerated: 6 months		
Freq	uency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batc	h No.	IB-001	IB-002	IB-003
Batc	h Size	500 Vials	500 Vials	500 Vials
Man	ufacturing Date	02-2022	02-2022	02-2022
Date	of Initiation	02-02-2022	03-02-2022	03-02-2022
No. o	of Batches		03	
	DOCUMENTS / DATA	TO BE PROVIDED A	ALONG WITH STABILI	TY STUDY DATA
1.	Reference of previous apprestability study data of the fi		th N/A	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Pb.2021/4570) dated 1 & Drugs Administra	9-07-2021, issued by Food ation Punjab India. The at the firm is operating at
3.	Documents for the procurement of API with approval from DRAP (in case of import).		th Not submitted.	
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 HF audit trail reports on produc			LC system along with audit
6.	Record of Digital data log humidity monitoring of stab and accelerated)			ord of digital data logger for lity monitoring of real time y chambers.

- 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

<u>Case No.: Registration applications of New Section of Human drugs on Form 5-F (Local)</u>
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.	Sections	
No.		
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: Racecadotril10mg
	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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 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.

J		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 l	Lot No.	2RAC0480622			
Description of Pack (Container closure system)		Sachet			
Stability Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	iency	Accelerated: 0, 3, 6 (Mo			
Batcl	ı No.	T-04	T-05	T-06	
Batcl	n Size	1500 Sachet	1500 Sachet	1500 Sachet	
Manı	ıfacturing Date	01-2023	01-2023	01-2023	
Date	of Initiation	12-01-2023	12-01-2023	12-01-2023	
No. o	of Batches	03			
	DOCUMENTS / DATA	TO BE PROVIDED A	LONG WITH STABIL	ITY STUDY DATA	
1.	Reference of previous app stability study data of the		h N/A		
2.	Approval of API/ DML/ manufacturer issued by authority of country of ori	concerned regulator			
3.		Documents for the procurement of API with approval from DRAP (in case of import).		h Drug substance clearance is in the name of Ma Weather fold Pharmaceuticals, Hattar instead of Ma 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.				
5.	.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		rtificate of 21 CFR compliance along with audit trail report for	
6.	Record of Digital data lo	gger for temperature an	d Firm has submitted re	ecord of digital data logger for	

time and accelerated)

- 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.

humidity monitoring of stability chambers (real temperature and humidity monitoring of real time and

accelerated stability chambers.

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: Racecadotril30mg
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 Laboratorie 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-PI template. Firm has summarized information relate to nomenclature, structure, general properties solubilities, physical form, manufacturers description of manufacturing process and controls specifications, analytical procedures and it validation, batch analysis and justification of specification, reference standard, container closur system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance darelated to nomenclature, structure, gener properties, solubilities, physical formanufacturers, description of manufacturing process and controls, specifications, analytic procedures and its validation, batch analysis and

Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product:			ification, reference standard, stem and stability studies of	
		of drug substance at b time conditions. The conducted at 40°C ±	ability study data of 3 batches oth accelerated as well as real accelerated stability data is 2°C / 75% ± 5% RH for 6 estability data is conducted at % RH for 12 months.	
		its description, codevelopment, manufal and process control, control of excipient specifications, analytical procedures,	ata of drug product including omposition, pharmaceutical acture, manufacturing process process validation protocols, s, control of drug product, acal procedures, validation of batch analysis, justification of ence standard or materials, em 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 va	llidation/verification o		analytical method validation g substance as well as drug	
STABILITY ST		UDY 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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency Accelerated: 0, 3, 6 (Mor Real Time: 0, 3, 6 (Mont				
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 STUI			ITY STUDY DATA	

Reference of previous approval of applications with stability study data of the firm (if any)	N/A
* *	
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.
	¥
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.
	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
	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. 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

- 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 M/s Wezen Pharmaceuticals, **Authorization Holder** 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 ☐ 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 Each capsule contains: Racecadotril...100mg Pharmaceutical ingredient (API) per unit 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 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.

	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 product		lidation/verification o		analytical method validation g substance as well as drug	
	1	STABILITY ST	TUDY DATA		
Manuf	acturer of API		, Phase III, I.D.A, Jeedim alkajgiri (Dist) -500 055 T	netla (Village), Quthbullalpur Felangana, India.	
API Lo	ot No.	2RAC0480622			
	ption of Pack iner closure system)	Sachet			
Stabili	ty Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time F	Period	Real time: 6 months Accelerated: 6 months			
Freque	ency	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	
Manuf	acturing Date	01-2023	01-2023	01-2023	
Date of	f Initiation	12-01-2023	12-01-2023	12-01-2023	
No. of Batches		03			
	DOCUMENTS / DATA	TO BE PROVIDED A	LONG WITH STABIL	ITY STUDY DATA	
1.	Reference of previous appr stability study data of the f	irm (if any)			
2.	Approval of API/ DML/Omanufacturer issued by authority of country of orig	concerned regulator			
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.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			lytical record for product	
5. Compliance Record of HP audit trail reports on produc				ificate of 21 CFR compliance ong with audit trail report for	
6.	Record of Digital data log humidity monitoring of s time and accelerated)			ord of digital data logger for ty monitoring of real time and ambers.	
Remar	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.

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.	Sections	
No.		
5.	Liquid Ampoule (General)	
6.	Liquid Injectable Vial SVP (General)	
7.	7. Eye/Ear Drop (General)	
8.	Eye Ointment (General)	

Following 03 applications have been submitted by the firm for registration: -

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 18 th 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.			vt. Ltd. Plot # C-7/1, North Port Qasim, Karachi, Pakistan	
Module-II (Quality Overall Sum		ıll Summary)	Firm has submitted template.	QOS as per WHO QOS-PD
	Module-III Drug Substan	ce:	Firm has submitted deper module 3.2.S.	etailed drug substance data as
	Stability Studies of Drug (Conditions & duration o			ability study data of 3 batches er zone IV-A conditions.
	Module-III Drug Product	:	Firm has submitted module 3.2.P.	data of drug product as per
	Pharmaceutical Equival Dissolution Profile	ence and Comparativ		pharmaceutical equivalence of Provas Infusion of M/s Sami
Analytical method validation/verification of laproduct			analytical method validation ig substance as well as drug	
	•	STABILITY S	TUDY DATA	
Manu	facturer of API	M/s. Saakh Pharma P Qasim, Karachi, Pakis		rth West Industrial Zone, Port
API L	ot No.	23GN6-10094		
	iption of Pack ainer closure system)	Glass vial		
Stabil	ity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequ	ency	Accelerated: 0, 3, 6 (Meal Time: 0, 3, 6 (Meal	' - '	
Batch No.		PAR-TB-001	PAR-TB-002	PAR-TB-003
Batch	Size	30L	30L	30L
Manu	facturing Date	05-2023	05-2023	05-2023
No. of	f Batches		03	
	DOCUMENTS / DATA	TO BE PROVIDED A	ALONG WITH STABIL	ITY STUDY DATA
1.	Reference of previous app stability study data of the		th N/A	
		ry DRAP Karachi issu	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		
		ns, testing.	alytical record for product	
5. Compliance Record of HPLC software 21CFR & laudit trail reports on product testing			rtificate of 21 CFR compliance along with audit trail report for	

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) Firm has submitted record of temperature and humidity monitoring accelerated stability chambers			
Re	Sr No.	ks of Evaluator: 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		

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

substance.

I. M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, A.JK.

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.	23 10
	(General)	
	Oral Powde	r Section-I Vet. (General)
	(19 Pro	ducts/ 10 Molecules)
343.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
343.	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	ARCH NEO 72 WSP
	Strength	ARCHINEO 12 WSF
	Composition	Each gram contains:
	Composition	Neomycin Sulphate720mg
	Diary No. Date of R& I & fee	Dy.No 3271 dated 20-02-2024 Rs 30,000/- dated 20-02-
	Blary No. Bate of Nee 1 & 1ee	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 /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	ARCH NEO 100 WSP
	Strength	
	Composition	Each gram contains:
		Neomycin Sulphate1000mg
	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.	,,, <u></u>
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 Chloride70gm Methionine10gm
	Di N. D. CD0 10 C	Sorbitol5gm Vitamin A150,000 IU Vitamin C10gm
	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 HC1200gm Neomycin Sulphate200gm Colistin Sulphate240MIU
	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 HCl80mg Neomycin Sulphate70mg Colistin Sulphate4mg

	Pharmacological Group Type of Form Finished product Specification	Form 5 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 HCl300mg Neomycin Sulphate150mg Florfenicol100mg
	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	
2.40	Decision: Approved.	N/
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 Florfenicol100mg
	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	
Ī	Decision: Approved.	
350.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,

	T	1 1
	Brand Name +Dosage Form + Strength	CRD Arch 40 Oral Powder
	Composition	Each gram contains:
		Doxycycline HCl400mg
		Tylosin tartrate200mg
		Colistin sulphate0.5MIU
		Bromhexine HCl10mg
	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.,
	Ne too status	Islamabad. (Reg. No. 088045)
	GMP status	New DML
	Remarks of the Evaluator	
	Remarks of the Evaluator	Target species: Calves, goats, sheep, poultry
	Decision: Approved.	Carves, goats, sneep, pourtry
351.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
351.		
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	CRD Arch 20 Oral Powder
	Strength	
	Composition	Each gram contains:
		Doxycycline HCl200mg
		Tylosin tartrate100mg
		Colistin sulphate0.5MIU
		Bromhexine HCl5mg
	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 /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	CRD Arch 13 Oral Powder
	Strength	
	Composition	Each gram contains:
	Composition	Doxycycline HCl130mg
		Tylosin tartrate170mg
		Colistin sulphate30mg
	D' M D (CDO LO C	Bromhexine HCl5mg
	Diary No. Date of R& I & fee	Dy.No 3282 dated 20-02-2024 Rs 30,000/- dated 20-02-
	71 1 1 2	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 /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Arch Fortyl Forte Oral Powder
	Composition	Each gram contains:
		Fosfomycin Calcium200mg
		Tylosin as Tartrate100mg
		Fructose 1,6 Diphosphate180mg
		Sodium Phosphate150mg
	Diamente Dete «CD 0 I 0 C	Magnesium Phosphate100mg
	Diary No. Date of R& I & fee	Dy.No 3277 dated 20-02-2024 Rs 30,000/- dated 20-02-
	Pharmacological Group	2024 (Slip No. 95534096212) Antibacterial
	Pharmacological Group 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
	No too status	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 /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Arch Dox 50% Water Soluble Powder
	Strength	
	Composition	Each gram contains:
	Diary No. Date of R& I & fee	Doxycycline Hyclate500mg Dy.No 3283 dated 20-02-2024 Rs 30,000/- dated 20-02-
	Diary No. Date of R& 1 & fee	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:
	D	Dogs, cats, horses
255	Decision: Approved.	M/s A selected Discourse of a Doct of Discourse of CO.D.
355.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant Brand Name +Dosage Form +	Small Industrial Estate, Bhimber, AJK. Arch Dox 80% Water Soluble Powder
	Strength	AICH DOX 6070 Water Soluble Fowder
	Composition	Each gram contains:
		Doxycycline Hyclate923.32mg (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.	18,
356.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	ARCOL 48% Oral Powder
	Strength	TIREOL 4070 Olai I Owdei
	Composition	Each gram contains:
	Composition	Colistin Sulphate48,00,000IU
	Diamy No. Data of D & I & foo	
	Diary No. Date of R& I & fee	Dy.No 3285 dated 20-02-2024 Rs 30,000/- dated 20-02-
	DI 1 1 1 C	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.	7 7 7
357.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	ARCOL 60% Oral Powder
	Strength	THEOD 00/0 OIGHT OWNER
	Composition	Each gram contains:
	Composition	Colistin Sulphate6,000,000IU
	Diary No. Date of R& I & fee	Dy.No 3286 dated 20-02-2024 Rs 30,000/- dated 20-02-
	Dialy No. Date of R& 1 & Ice	2024 (Slip No. 49313818259)
	Pharmacological Group	Antibacterial
	<u> </u>	Form 5
	Type of Form	
	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.	1 O
358.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
550.	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	ARCOL 55% Oral Powder
	Diana Maine TDOSage POIIII +	THEOL 33/0 Oral I OWAGI
	Strength	
	Strength Composition	Each Kg contains:

		Colictia Sylphoto 550MILI
	Diama Na Data af D.O. L.O. fa	Colistin Sulphate550MIU
	Diary No. Date of R& I & fee	Dy.No 3287 dated 20-02-2024 Rs 30,000/- dated 20-02-
	Di 1 : 1 C	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 /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	ARCH CTC 20% Water Soluble Powder
	Strength	
	Composition	Each gram contains:
		Chlortetracycline HCl200mg
	Diary No. Date of R& I & fee	Dy.No 3288 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 568549968790)
	Dhammaadariad Cusum	2024 (Shp No. 308349908790) Antibacterial
	Pharmacological Group	
	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.	2050, 0410, 1101000
360.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
300.	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	ARCH CTC 25% Water Soluble Powder
	Strength	ARCH CTC 25% water soluble Fowder
	Composition	Each gram contains:
	Composition	Chlortetracycline as HCl250mg
	Diary No. Date of R& I & fee	Dy.No 3289 dated 20-02-2024 Rs 30,000/- dated 20-02-
	Diary No. Date of R& 1 & Ice	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
	There size & Demanded	25000gm; Decontrolled
	Me-too status	Meralin 250 Water Soluble Powder of M/s. Mylab (Pvt)
	1120 000 000000	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 /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant Applicant	Small Industrial Estate, Bhimber, AJK.
	I II	

	Brand Name +Dosage Form +	Arch Fursa Oral Powder
	Strength	E 1 1000
	Composition	Each 1000gm contains:
		Furosemide20gm
		Sodium Chloride35gm
		Magnesium Sulphate35gm
		Manganese Sulphate1gm
		Calcium Carbonate45gm
		Potassium Chloride400mg
	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:
	Remarks of the Evaluator	Calves, goats, sheep, poultry
	Decision: Approved.	Carves, goats, sneep, pountry
		II (General) Vet. Section
		ducts/ 10 molecules)
362.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Arch Zen Drench
	Strength	
	Composition	Each 100ml contains:
		Oxyclozanide3.0gm
		Levamisole HCl1.50gm
		Sodium Selenite0.167gm
		Cobalt Sulphate0.05gm
	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
	112 655 56465	(Pvt) Ltd.,Lahore (Reg. No. 075641)
	GMP status	New DML
	Remarks of the Evaluator	Target species:
	Remarks of the Evaluation	Cattle, Calves, sheep, goats
	Decision: Approved.	cante, carres, sheep, goals
363.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Arch Zen Forte Drench
	Strength	Then Zon I one Dienen
	Composition	Each 100ml contains:
	Composition	Oxyclozanide6.0gm
		Levamisole HCl3.0gm
		Sodium Selenite0.076gm
		Cobalt Sulphate0.764gm

	Pharmacological Group	2024 (Slip No. 14653468340) 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:
	Decision: Approved.	Cattle, Calves, sheep, goats
364.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
304.	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Arch Ben 2.5% Drench
	Strength	Alen Ben 2.5 % Dienen
	Composition	Each 100ml contains:
	1	Albendazole2.5gm
		Sodium Selenite0.035gm
		Cobalt Sulphate0.075gm
	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,
	GI (D	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 /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Arch Ben 12.5% Drench
	Strength	
	Composition	Each 100ml contains:
		Albendazole12.5gm
		Sodium Selenite0.035gm
		Cobalt Sulphate0.382gm
	Diary No. Date of R& I & fee	Dy.No 3261 dated 20-02-2024 Rs 30,000/- dated 20-02-
	N 1 : 1 C	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)
1	GMP status	New DML
	Sivil Status	
	Remarks of the Evaluator	Target species:
		Target species: Calves, sheep, goats

366.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
300.	Applicant Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Arch Ox 2.265% Drench
	Strength	Then GA 2.260 /V Brenen
	Composition	Each 100ml contains:
	Composition	Oxfendazole2.265gm
		Sodium Selenite0.030gm
		Cobalt Chloride0.075gm
	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;
	Tuck Size & Bellianded	Decontrolled
	Me-too status	Fenzole CS Suspension of M/s. Attabak Pharmaceutical
	We too status	Islamabad (Reg. No. 058901)
	GMP status	New DML
	Remarks of the Evaluator	Target species:
	Remarks of the Evaluator	Cattle, calves, sheep, goats, horses
	Decision: Approved.	Cuttle, curves, sheep, gouts, noises
367.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
307.	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Clofen Drench
	Strength	Civicii Biciicii
	Composition	Each ml contains:
	Composition	Oxyclozanide62.5mg
		Oxfendazole22.65mg
		Sodium Selenite0.5mg
		Cobalt Sulphate1.67mg
	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.	1 / 1/0 /
368.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Arch Skol oral suspension
	Strength	
	Composition	Each ml contains:
		Sulphadiazine35.50mg
		Sulphadimidine28.40mg
		Neomycin Sulphate1.80mg
		Hyoscine N Butylbromide0.04mg
		Pectin7.10mg
		Kaolin103.30mg
		Vitamin B10.15mg
		Vitamin B20.22mg

	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.	Cattle, camends, sneep, goats, noises
369.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
307.	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Arch Leva 1.5% Drench
	Strength	Arch Leva 1.5% Diench
	Composition	Each 100ml contains:
	Composition	Levamisole HCl1.5gm
	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.	7 7 170
370.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Clazole 5% Suspension
	Strength	
	Composition	Each 100ml contains:
	The state of the s	Triclabendazole5%
		Levamisole HCl3.75%
		Sodium Selenite0.035%
		Cobalt Chloride0.075%
	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
	I mished product specification	* *
	Pack size & Demanded	100ml 150ml 250ml 500ml 11 iter 2.51 iter
	Pack size & Demanded	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter;
		Decontrolled
	Pack size & Demanded Me-too status	Decontrolled Trizen 8.75 Oral Liquid of M/s. Elegance
	Me-too status	Decontrolled Trizen 8.75 Oral Liquid of M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 078284)
	Me-too status GMP status	Decontrolled Trizen 8.75 Oral Liquid of M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 078284) New DML
	Me-too status	Decontrolled Trizen 8.75 Oral Liquid of M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 078284) New DML Target species:
	Me-too status GMP status Remarks of the Evaluator	Decontrolled Trizen 8.75 Oral Liquid of M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 078284) New DML
251	Me-too status GMP status Remarks of the Evaluator Decision: Approved.	Decontrolled Trizen 8.75 Oral Liquid of M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 078284) New DML Target species: Cattle, calves, sheep, goats
371.	Me-too status GMP status Remarks of the Evaluator	Decontrolled Trizen 8.75 Oral Liquid of M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 078284) New DML Target species:

	T= 432 = =	T = 1 + 1 + 1 + 1 + 1 + 1 + 1 + 1 + 1 + 1
	Brand Name +Dosage Form + Strength	Clazole 12% Suspension
	Composition	Each ml contains:
		Triclabendazole120mg
		Levamisole HCl75mg
		Sodium Selenite0.35mg
		Cobalt Chloride0.75mg
	Diama Na Data af D.O. L.O. Car	
	Diary No. Date of R& I & fee	Dy.No 3267 dated 20-02-2024 Rs 30,000/- dated 19-02-
	7	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 /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Mecben Drench
	Strength	
	Composition	Each 100ml contains:
	Composition	Triclabendazole12gm
		Ivermectin0.2gm
		Albendazole10gm
	Diary No. Date of R& I & fee	Dy.No 3268 dated 20-02-2024 Rs 30,000/- dated 19-02-
	Diary No. Date of R& 1 & Ice	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;
	Fack Size & Demanded	Decontrolled
	Mataratata	
	Me-too status	Thunder Drench of M/s. Star Laboratories (Pvt) Ltd,
	C) (D)	Lahore (Reg. No. 058941)
	GMP status	New DML
	Remarks of the Evaluator	Target species:
		Cattle, calves, sheep, goats
252	Decision: Approved.	M/, A a lead Discourse Cod Division Division 27 00 /D
373.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Arch Clo Suspension
	Strength	F 1 100 1
	Composition	Each 100ml contains:
	D. M. D. (DOVO)	Oxyclozanide3.4%
	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.	T. W. C.
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 +	Arch Oxal oral suspension
	Strength	Arch Ozai orai suspension
	Composition	Each litre contains:
		Oxfendazole22.65gm
		Triclabendazole85gm
	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;
	Tack Size & Bellianded	Decontrolled
	Me-too status	Vorcid Suspension of M/s. Breeze Pharma (Pvt.) Ltd.,
	1120 60 0 0000000	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 Pro	ducts/ 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 +	ARCH LEV 15% Powder
	Strength	
	Composition	Each 100gm contains:
	_	Levamisole HCl15gm
	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.
		ovator's specifications. Firm shall submit Rs. 7500/- for cations before issuance of registration letter.
376.	Name and address of manufacturer /	cations before issuance of registration letter.
3/0.		M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant Prend Name Desega Form	Small Industrial Estate, Bhimber, AJK. ARCH LEV 20% Powder
	Brand Name +Dosage Form +	ARCH LEV 2070 FUWUCI
1	Strength	

	Composition	Each 100gm contains:
		Levamisole HCl20gm
	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:
	Remarks of the Evaluator	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
	Desisions Annuaged with as non-inne	issuance of registration letter. vator's specifications. Firm shall submit Rs. 7500/- for
		_
255		cations before issuance of registration letter.
377.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	ARCH LEV 50% Powder
	Strength	
	Composition	Each 100gm contains:
		Levamisole HCl50gm
	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:
	Tremains of the Evaluation	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 inno	vator's specifications. Firm shall submit Rs. 7500/- for
		cations before issuance of registration letter.
378.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
370.	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Archoban Powder
	~	Archoball I owder
	Strength	Fach arom contains:
	Composition	Each gram contains:
		Neomycin Sulphate33.33mg
		Streptomycin Sulphate33.33mg
		Sulphaguanidine333.33mg
		Pectin33.33mg
		Bismuth Subnitrate166.66mg
		Vitamin A Acetate2.291mg
		Kaolin333.33mg

	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:
	Temana of the Brandaror	Cattle, calves, sheep, goats, poultry
	Decision: Approved.	
379.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
0.71	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Archoban Forte Powder
	Strength	Attenobali i ofte i owaci
	Composition	Each 12gram contains:
	Composition	Neomycin Sulphate400mg
		Streptomycin Sulphate400mg
		Sulphaguanidine4000mg
		Pectin400mg
		Bismuth Subnitrate2000mg
		Vitamin A Acetate80000 I.U.
	Diamy No. Data of D % I % for	Kaolin400gm
	Diary No. Date of R& I & fee	Dy.No 3295 dated 20-02-2024 Rs 30,000/- dated 20-02-
	N 1 1 1 G	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.	1,5,1
380.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Gasiton Powder
	Strength	
	Composition	Each 1000gm contains:
	P	Propionic Acid Calcium250gm
		Propionic Acid Sodium400gm
		Acetanilide150gm
		Magnesium Oxide125gm
		Iron II Sulphate400mg
		Zinc Sulphate100mg
		Magnesium Sulphate200mg
		Copper Sulphate450mg
		Cobalt Sulphate400mg
		Sodium Molybdate100mg
	Diam No Data of DO TO for	Sodium Chloride20gm
	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 /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Arch Linco 11 Pre Mix
	Strength	
	Composition	Each gram contains:
		Lincomycin HCl11mg
	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.
		rand name. Firm shall submit fee Rs. 30,000/- for revision
		product as prescribed vide S.R.O. 496(I)/2023 dated 17-
	04-2023 before issuance of registration	
382.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Arch Linco 44 Pre Mix
	Strength	
	Composition	Each gram contains:
		Lincomycin HCl44mg
	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
	76	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
	1	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.
		and name. Firm shall submit fee Rs. 30,000/- for revision product as prescribed vide S.R.O. 496(I)/2023 dated 17-
383.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B, Small Industrial Estate, Bhimber, AJK. Stone Fon 96 Powder
	Composition	Each gram contains: Trichlorfon960mg
	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 Pack size & Demanded	As per innovator's Specifications 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
20.4	Decision: Approved.	N/ A 1 1D
384.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant Brand Name +Dosage Form +	Small Industrial Estate, Bhimber, AJK. Stone Fon 98 Powder
	Strength	Stolic Foli 76 Fowder
	Composition	Each gram contains: Trichlorfon980mg
	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
20.5	Decision: Approved.	N/
385.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant Brand Name +Dosage Form +	Small Industrial Estate, Bhimber, AJK. Arch Colin Powder
	Strength	
	Composition	Each gram contains: Lincomycin HCl100mg Colistin Sulphate800000IU
	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

	T	T
	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:
	Tremains of the Evaluation	Poultry
	Decision: Approved.	
386.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ampro Arch 20% Powder
	Composition	Each gram contains: Amprolium HC1200mg
	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 /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ampro Arch 50% Powder
	Composition	Each gram contains:
	•	Amprolium HCl500mg
	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 /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ampro Arch 90% Powder
	Composition	Each gram contains:
	Composition	Amprolium HCl900mg
	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
	1 - 1 0 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -	1

	Einist at any fact Consider	LICD Constitutions
	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 +	Strep Dox 20 Powder
	Strength	•
	Composition	Each gram contains:
		Doxycycline HCl200mg
		Tylosin Tartrate100mg
		Dihydrostreptomycin20mg
		Bromhexine HCl5mg
	Diary No. Date of R& I & fee	Dy.No 3305 dated 20-02-2024 Rs 30,000/- dated 20-02-
	Diary No. Date of Ree 1 ee 1ce	2024 (Slip No. 5255551920)
	Pharmacological Group	Antibacterial
	<u> </u>	Form 5
	Type of Form	
	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 /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Strep Dox 40 Powder
	Strength	
	Composition	Each gram contains:
	Composition	Doxycycline HCl200mg
		T I VIOSIN TARIFATE TOUMO
		Tylosin Tartrate100mg
		Dihydrostreptomycin40mg
	Diary No. Data of P& I & fac	Dihydrostreptomycin40mg Bromhexine HCl5mg
	Diary No. Date of R& I & fee	Dihydrostreptomycin40mg Bromhexine HCl5mg Dy.No 3306 dated 20-02-2024 Rs 30,000/- dated 20-02-
	,	Dihydrostreptomycin40mg Bromhexine HCl5mg Dy.No 3306 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 629094274)
	Pharmacological Group	Dihydrostreptomycin40mg Bromhexine HCl5mg Dy.No 3306 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 629094274) Antibacterial
	Pharmacological Group Type of Form	Dihydrostreptomycin40mg Bromhexine HCl5mg Dy.No 3306 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 629094274) Antibacterial Form 5
	Pharmacological Group Type of Form Finished product Specification	Dihydrostreptomycin40mg Bromhexine HCl5mg Dy.No 3306 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 629094274) Antibacterial Form 5 As per innovator's specifications
	Pharmacological Group Type of Form	Dihydrostreptomycin40mg Bromhexine HCl5mg Dy.No 3306 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 629094274) Antibacterial Form 5 As per innovator's specifications 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, and 25000gm; Decontrolled
	Pharmacological Group Type of Form Finished product Specification	Dihydrostreptomycin40mg Bromhexine HCl5mg Dy.No 3306 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 629094274) Antibacterial Form 5 As per innovator's specifications 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm,
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	Dihydrostreptomycin40mg Bromhexine HCl5mg Dy.No 3306 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 629094274) Antibacterial Form 5 As per innovator's specifications 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, and 25000gm; Decontrolled Tylobrom-S Powder of M/s Attabak Pharmaceuticals,
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	Dihydrostreptomycin40mg Bromhexine HCl5mg Dy.No 3306 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 629094274) Antibacterial Form 5 As per innovator's specifications 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, and 25000gm; Decontrolled Tylobrom-S Powder of M/s Attabak Pharmaceuticals, Islamabad (Reg. No.075698) New DML Target species:
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator	Dihydrostreptomycin40mg Bromhexine HCl5mg Dy.No 3306 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 629094274) Antibacterial Form 5 As per innovator's specifications 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, and 25000gm; Decontrolled Tylobrom-S Powder of M/s Attabak Pharmaceuticals, Islamabad (Reg. No.075698) New DML
201	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved.	Dihydrostreptomycin40mg Bromhexine HCl5mg Dy.No 3306 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 629094274) Antibacterial Form 5 As per innovator's specifications 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, and 25000gm; Decontrolled Tylobrom-S Powder of M/s Attabak Pharmaceuticals, Islamabad (Reg. No.075698) New DML Target species: Calves, goats, sheep, poultry
391.	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator	Dihydrostreptomycin40mg Bromhexine HCl5mg Dy.No 3306 dated 20-02-2024 Rs 30,000/- dated 20-02-2024 (Slip No. 629094274) Antibacterial Form 5 As per innovator's specifications 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, and 25000gm; Decontrolled Tylobrom-S Powder of M/s Attabak Pharmaceuticals, Islamabad (Reg. No.075698) New DML Target species:

	Brand Name +Dosage Form +	Arch Med W/S Powder
	Strength Composition	Each 100cm contains
	Composition	Each 100gm contains:
		Methenamine95gm Vitamin B1800mg
		Vitamin B1920mg
		Vitamin B2920fig Vitamin K3200mg
	Diamy No. Data of D & I & foo	Dy.No 3307 dated 20-02-2024 Rs 30,000/- dated 20-02-
	Diary No. Date of R& I & fee	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,
	No.	and 25000gm; Decontrolled
	Me-too status	Renofic Oral Powder of M/s Biorific Pharma,
	GMP status	Islamabad (Reg. No. 117286) New DML
	Remarks of the Evaluator	
	Remarks of the Evaluator	Shortcomings:
		clarification regarding solubility of instant formulation
		egarding solubility of instant formulation.
392.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Spiro Spec Powder
	Strength	
	Composition	Each 100gm contains:
		Lincomycin HCl5gm
		Spectinomycin HCl7.5gm
		Spiramycin Adipate2.5gm
		Bromhexine HCl0.5gm
	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
		stration Board advised the applicant to clearly mention
	specific target species on label.	Cartina IV-A (Carana)
	Orai Liquid	Section-I Vet. (General)
	(23 Pro	ducts/ 10 Molecules)
393.	Name and address of manufacturer /	M/s Archard Pharmaceuticals Pvt Ltd., Plot No. 27-28/B,
	Applicant	Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form +	Arch Til Liquid
	Strength	1" "
	Composition	Each 100ml contains:
	Composition	Lacii 100iiii Contains.

Diary No. Date of R& I & fee Dy.No 3235 dated 20-02-2024 Rs 30,0	
2024 (Slip No. 2444535711)	,000/- dated 19-02-
Pharmacological Group Antibiotic	
Type of Form Form 5	
Finished product Specification	
Pack size & Demanded 100ml, 150ml, 250ml, 500ml, 1000ml Decontrolled	l, and 2500ml;
Me-too status Tilco Mal Liquid of M/s Mallard Phar Ltd., Multan (Reg. No. 118612)	rmaceuticals (Pvt)
GMP status New DML	
Remarks of the Evaluator Target species:	
Calves, broilers, turkeys	
Shortcomings:	
Firm shall submit fee Rs. 30,000/- for claim in line with reference product S.R.O. 496(I)/2023 dated 17-04-2023.	t as prescribed vide
	l alaime im lima muidh
Decision: Approved. Firm shall submit fee Rs. 30,000/- for revision of label reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 registration letter.	
reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023	before issuance of d., Plot No. 27-28/B,
reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 registration letter. 394. Name and address of manufacturer / M/s Archard Pharmaceuticals Pvt Ltd.	before issuance of d., Plot No. 27-28/B,
reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 registration letter. 394. Name and address of manufacturer / Applicant Small Industrial Estate, Bhimber, AJK Brand Name +Dosage Form + Arch Fen 20% Liquid	before issuance of d., Plot No. 27-28/B,
reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 registration letter. 394. Name and address of manufacturer / Applicant M/s Archard Pharmaceuticals Pvt Ltd. Small Industrial Estate, Bhimber, AJK Brand Name +Dosage Form + Arch Fen 20% Liquid	before issuance of d., Plot No. 27-28/B,
reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 registration letter. Name and address of manufacturer / Applicant	before issuance of d., Plot No. 27-28/B, K.
reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 registration letter. 394. Name and address of manufacturer / Applicant	before issuance of d., Plot No. 27-28/B, K.
reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 registration letter. 394. Name and address of manufacturer / Applicant	before issuance of d., Plot No. 27-28/B, K.
reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 registration letter. 394. Name and address of manufacturer / Applicant	before issuance of d., Plot No. 27-28/B, K.
reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 registration letter. 394. Name and address of manufacturer / Applicant	before issuance of d., Plot No. 27-28/B, K.
reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 registration letter. 394. Name and address of manufacturer / Applicant Small Industrial Estate, Bhimber, AJK Small Industrial Estate, Bhimber, AJK Strength Arch Fen 20% Liquid Strength Composition Each 100ml contains: Florfenicol20gm Diary No. Date of R& I & fee Dy.No 3236 dated 20-02-2024 Rs 30,4 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	d., Plot No. 27-28/B, K. ,000/- dated 19-02-
reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 registration letter. 394. Name and address of manufacturer / Applicant	d., Plot No. 27-28/B, K. ,000/- dated 19-02-
reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 registration letter. 394. Name and address of manufacturer / Applicant	d., Plot No. 27-28/B, K. ,000/- dated 19-02-

		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: Florfenicol23gm
	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:
		Florfenicol250mg
	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:
		Florfenicol10gm
		Colistin Sulphate50MIU
	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:
		Florfenicol230gm
		Colistin Sulphate500MIU
	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:
		Florfenicol25gm
		Colistin Sulphate50MIU
	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:
		Trimethoprim80mg

		Sulphadiazine400mg
	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 su specifications before issuance of regist	bmit Rs. 7500/- for correction in finished product tration 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 HCl10mg
	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.	1
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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 HC150mg
	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 HC120mg
	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:	
		Enrofloxacin100mg	
		Colistin Sulphate0.48 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:	
		Enrofloxacin200mg	
		Colistin Sulphate30mg	
	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:
		Enrofloxacin250mg
		Colistin Sulphate0.050 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:
		Enrofloxacin10gm
	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:
		Enrofloxacin20gm
	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:
		Enrofloxacin25gm
	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-Carnitine50mg
		Betaine20mg
		Choline Chloride100mg
		Inositol7mg
		Magnesium Sulphate10mg
		Sorbitol200mg
	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 HCl10mg
		Menthol20mg

	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 HCl20mg
		Menthol40mg
	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:
L	1	

		Bromhexine HCl50mg
		Menthol40mg
	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:
		Albendazole25mg
		Closantel5mg
	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 +	ARCH Clozol 10 Suspension
Strength	
Composition	Each ml contains:
	Albendazole100mg
	Closantel20mg
Diary No. Date of R& I & fee	Dy.No 3257 dated 20-02-2024 Rs 30,000/- dated 19-
	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. 1113
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)	17	10			
	Vet.					
Ovel Liquid Section (Conovel) Vet						

Oral Liquid Section (General) Vet. (17 Products/ 10 Molecules) M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2, 416. Name and address of manufacturer / **Applicant** National Industrial Zone, Rawat. Brand Name +Dosage Form + Soc-Nix Plus Drench Strength Composition Each ml contains: Oxyclozanide.....94mg Oxfendazole.....34mg Cobalt Sulphate......3.82mg Sodium Selenite......0.50mg RGX-5PV-U7GS dated 08-03-2024 Rs 30,000/- dated Tracking ID, date & fee 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
	Tito too status	(Pvt.) Ltd, Bhimber, AJK (Reg. No. 119726)
	GMP status	New DML
	Remarks of the Evaluator	Target species:
		Livestock, poultry
	Decision: Approved, Moreover, Regis	stration 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 +	Soc-Nix Super Drench
	Strength	•
	Composition	Each ml contains:
	•	Oxyclozanide62.50mg
		Oxfendazole25mg
		Cobalt Sulphate2mg
		Sodium Selenite0.50mg
	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
		62.50gm/ml, the firm has now revised formulation as
		per following label claim:
		Each ml contains:
		Oxyclozanide62.50mg
		Oxfendazole25mg
		Cobalt Sulphate2mg
		Sodium Selenite0.50mg
		The firm has NOT submitted fee for revision of
		formulation.
		ait 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
		ration Board advised the applicant to clearly mention
	specific target species on label.	T
418.	Name and address of manufacturer /	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,
	Applicant	National Industrial Zone, Rawat.
	Brand Name +Dosage Form +	Los-Nix DS Suspension
	Strength	
	Composition	Each 100ml contains:
		Oxyclozanide30mg
		Levamisole HCl15mg
		Cobalt Chloride
		Sodium Selenite3.5mg
		-
	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,
	Tuck Size & Bellianded	2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Roldzen DS Oral Suspension of M/s. Haarolds
	NIC-too status	Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No.
		109064)
	GMP status	New DML
	Remarks of the Evaluator	
	Remarks of the Evaluator	Target species:
	Designar Ammunud Managuar Designar	Livestock, poultry
		tration Board advised the applicant to clearly mention
419.	specific target species on label. Name and address of manufacturer /	M/s Pharmanin Pharmanauticals Plat 20 Ctract CC 2
419.		M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,
	Applicant	National Industrial Zone, Rawat.
	Brand Name +Dosage Form +	Los-Nix SC Suspension
	Strength	7. 1.100 1
	Composition	Each 100ml contains:
		Oxyclozanide6gm
		Levamisole HCl3gm
		Cobalt Chloride0.15gm
		Sodium Selenite0.07gm
	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,
	Tack Size & Demanded	2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Roldzen Super Suspension of M/s. Haarolds
	Wie-too status	Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No.
		109067)
	GMP status	New DML
	Remarks of the Evaluator	Target species:
	Remarks of the Evaluator	Livestock, poultry
	Designer Approved Manager Pagis	stration Board advised the applicant to clearly mention
	specific target species on label.	tration board advised the applicant to clearly mention
420.	Name and address of manufacturer /	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,
420.		
	Applicant	National Industrial Zone, Rawat.
	Brand Name +Dosage Form +	Hpk-Nix Suspension
	Strength	
	Composition	Each ml contains:
		Sulphadiazine35.5mg
		Sulphadimidine28.4mg
		Neomycin Sulphate1.8mg
		Hyoscine Methylbromide0.04mg
		Pectin7.1mg
		Kaolin103.3mg
		Vitamin B10.15mg
		Vitamin B20.22mg
		Vitamin B60.15mg
		Vitamin K34mg
	Tracking ID, date & fee	QTB-BV4-L22N dated 09-03-2024 Rs 30,000/- dated
	Tracking 112, dute & lee	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,
	Tack Size & Bellanded	2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Rexin Oral Suspension of M/s. Evergreen
	112 600 500000	Pharmaceuticals, Lahore. (Reg. No. 118400)
	GMP status	New DML
	Remarks of the Evaluator	TO DAIL
	Decision: Approved.	
421.	Name and address of manufacturer /	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,
	Applicant	National Industrial Zone, Rawat.
	Brand Name +Dosage Form +	MC-Nix Suspension
	Strength	
	Composition	Each 5ml contains:
	r	Closantel250mg
		Mebendazole375mg
	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 /	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,
	Applicant	National Industrial Zone, Rawat.
	Brand Name +Dosage Form +	Tl-Nix Forte Suspension
	Strength	1
	Composition	Each ml contains:
		Triclabendazole50mg
		Levamisole HCl37.5mg
		Cobalt Sulphate1.67mg
		Sodium Selenite0.35mg
	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
		stration Board advised the applicant to clearly mention
	specific target species on label.	
423.	Name and address of manufacturer /	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,
	Applicant	National Industrial Zone, Rawat.
	Brand Name +Dosage Form +	Ocs-Nix Suspension
	Strength	
	Composition	Each 100ml contains:
		Oxfendazole2.265gm

		Cobalt Sulphate
		Sodium Selenite
	Tracking ID, date & fee	YHH-PU2-71P1 dated 11-03-2024 Rs 30,000/- dated 07-
	N 1 : 10	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	
	Remarks of the Evaluator	Target species: Livestock, poultry
	Decision: Approved Moreover Regis	stration Board advised the applicant to clearly mention
	specific target species on label.	mutton Board advised the applicant to crearly mention
424.	Name and address of manufacturer /	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,
	Applicant	National Industrial Zone, Rawat.
	Brand Name +Dosage Form +	E.C.NIX 10/50 Oral Liquid
	Strength	1
	Composition	Each 100ml contains:
	1	Enrofloxacin10gm
		Colistin Sulphate50MIU
	Tracking ID, date & fee	W9G-RQ6-9X77 dated 11-03-2024 Rs 30,000/- dated
	<i>S</i> ,	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
		tration Board advised the applicant to clearly mention
	specific target species on label.	
425.	Name and address of manufacturer /	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,
	Applicant	National Industrial Zone, Rawat.
	Brand Name +Dosage Form +	E.C.NIX 20/3 Oral Liquid
	Strength	Fach will a minima
	Composition	Each ml contains:
		Enrofloxacin20%
	Tracking ID data & for	Colistin Sulphate3%
	Tracking ID, date & fee	QUN-R7T-ATVP dated 11-03-2024 Rs 30,000/- dated
	Pharmacological Group	07-03-2024 (Slip No. 70800006) Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml,
	1 ack Size & Demanded	2500ml, 500ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled
	Me-too status	Acmecoliflox 20/3 Oral Liquid of M/s. Acme
	1410-100 Status	Pharmaceuticals, Rawat, Islamabad. (Reg. No. 117019)
	GMP status	New DML
	Remarks of the Evaluator	Target species:
	Ternarks of the Lyandator	Livestock, poultry
		zirestori, poutuj

	Decision: Approved. Moreover, Regispecific target species on label.	stration Board advised the applicant to clearly mention	
426.	Name and address of manufacturer /	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,	
120.	Applicant Applicant	National Industrial Zone, Rawat.	
	Brand Name +Dosage Form +	E.C.NIX 20/50 Oral Liquid	
	Strength	2.61.11.20,00 014.214.14	
	Composition	Each 100ml contains:	
	r	Enrofloxacin20gm	
		Colistin Sulphate50MIU	
	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, Regi	stration Board advised the applicant to clearly mention	
	specific target species on label.	Tr .	
427.	Name and address of manufacturer /	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,	
	Applicant	National Industrial Zone, Rawat.	
	Brand Name +Dosage Form +	E.C.NIX 25/5 Oral Liquid	
	Strength	•	
	Composition	Each 100ml contains:	
		Enrofloxacin5gm	
		Colistin Sulphate25MIU	
	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 /	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,	
	Applicant	National Industrial Zone, Rawat.	
	Brand Name +Dosage Form +	Essitin Forte Oral Liquid	
	Strength	2557411 TOTAL STATE ZIGINA	
	Composition	Each ml contains:	
	2	Enrofloxacin75mg	
		Sulphamethoxypridazine50mg	
		Sulphamethazine50mg	
		Trimethoprim25mg	
	Tracking ID, date & fee	15A-E5E-HBQQ dated 12-03-2024 Rs 30,000/- dated	
	Tracking 1D, date & fee	07-03-2024 (Slip No. 03928157)	
	Pharmacological Group	Antibiotic	
	I narmacorogical Oroup	1 MILLOTOLIC	

Finished product Specification		Type of Form	Form 5
Pack size & Demanded Me-too status Me-too status Sulphacina Oral Liquid of M/s. Bio-Oxi Pharmaceuticals, Faisalabad. (Reg. No. 074786) GMP status Remarks of the Evaluator Target species: Livestock, poultry Decision: Approved. Moreover, Registration Board advised the applicant to clearly mentic specific target species on label. 429. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each ml contains: Enrofloxacin75mg Sulphamethoxypridazine75mg Sulphamethoxypridazine75mg Sulphamethoxypridazine75mg Sulphamethoxypridazine75mg Trimethoprim25mg 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 Pack size & Demanded 30ml, 50ml, 10ml, 12ml, 250ml, 50ml, 100ml, 2500ml, 500ml, 1000ml, 2500ml, 500ml, 100ml, 2500ml, 500ml, 100ml, 2500ml, 500ml, 100ml, 2500ml, 500ml, 100ml, 250ml, 100ml, 250ml, 100ml, 250ml, 100ml, 250ml, 100ml, 250ml, 100ml, 250ml, 500ml, 100ml, 250ml, 500ml, 500ml			
Me-too status			30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml,
Pharmaceuticals, Faisalabad. (Reg. No. 074786) GMP status Remarks of the Evaluator Remarks of the Evaluator Decision: Approved. Moreover, Registration Board advised the applicant to clearly mentic specific target species on label. 429. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each ml contains: Enrofloxacin75mg Sulphamethoxypridazine75mg Sulphamethoxypridazine75mg Sulphamethoxypridazine75mg Sulphamethoxypridazine50mg Trimethoprim50mg Trimethoprim50mg Trimethoprim55mg 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 Pack size & Demanded 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 2500ml, 5000ml, 2500ml, 5000ml, 2500ml, 5000ml, 2500ml, 2		Mo too status	
GMP status New DML		We-too status	1
Remarks of the Evaluator		C) (D)	
Livestock, poultry Decision: Approved. Moreover, Registration Board advised the applicant to clearly mentic specific target species on label. 429. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each ml contains: Enrofloxacin			15.77
Specific target species on label. A29. Name and address of manufacturer / Applicant M/s Pharmonix Pharmaceuticals, Plot 28, Street SS National Industrial Zone, Rawat.		Remarks of the Evaluator	
Name and address of manufacturer / Applicant M/s Pharmonix Pharmaceuticals, Plot 28, Street SS National Industrial Zone, Rawat.			istration Board advised the applicant to clearly mention
Applicant Brand Name +Dosage Form + Strength Composition Each ml contains: Enrofloxacin75mg Sulphamethoxypridazine75mg Sulphamethoxypridazine50mg Trimethoprim50mg Trimethoprim55mg 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 Pack size & Demanded 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 500ml, 500ml, 500ml, 2500ml, 500ml, 2500ml, 500ml, 2500ml, 500ml, 2500ml, 500ml, 1000ml, 2500ml, 500ml, Econtrolled Me-too status Entri SS Oral Liquid of M/s. Suave Pharmaceuticals F. 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 mentic specific target species on label. 430. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Flornix-10 Oral Liquid	429.		M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,
Brand Name +Dosage Form + Strength Composition Each ml contains: Enrofloxacin75mg Sulphamethoxypridazine75mg Sulphamethoxypridazine50mg Trimethoprim		Applicant	
Composition Each ml contains: Enrofloxacin		Brand Name +Dosage Form +	
Enrofloxacin75mg Sulphamethoxypridazine75mg Sulphamethoxypridazine75mg Sulphamethoxypridazine75mg Sulphamethoxypridazine75mg Sulphamethoxypridazine75mg Sulphamethoxypridazine75mg Trimethoprim25mg 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 Pack size & Demanded 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 2500ml, 5000ml, 2500ml, 5000ml, Decontrolled Me-too status Entri SS Oral Liquid of M/s. Suave Pharmaceuticals FLtd., 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 mentic specific target species on label. 430. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Flornix-10 Oral Liquid			Each ml contains:
Sulphamethoxypridazine75mg Sulphamethazine50mg Trimethoprim25mg 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 Pack size & Demanded 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 500ml, 500ml, 1000ml, 2500ml, 500ml, 2500ml, Decontrolled Me-too status Entri SS Oral Liquid of M/s. Suave Pharmaceuticals Factor, Khurianwala, Faisalabad (Reg. No. 117129) GMP status Remarks of the Evaluator Target species: Livestock, poultry Decision: Approved. Moreover, Registration Board advised the applicant to clearly mentions specific target species on label. 430. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Flornix-10 Oral Liquid		1	
Sulphamethazine50mg Trimethoprim25mg 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 Pack size & Demanded 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 5000ml, 2500ml, 5000ml, Decontrolled Me-too status Entri SS Oral Liquid of M/s. Suave Pharmaceuticals FLtd., 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 mentic specific target species on label. 430. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Flornix-10 Oral Liquid			
Trimethoprim25mg 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 Pack size & Demanded 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 2500ml, 5000ml, 2500ml, 5000ml, Decontrolled Me-too status Entri SS Oral Liquid of M/s. Suave Pharmaceuticals FLtd., 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 mentions specific target species on label. 430. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Flornix-10 Oral Liquid			
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 Pack size & Demanded Me-too status Entri SS Oral Liquid of M/s. Suave Pharmaceuticals F. Ltd., Khurianwala, Faisalabad (Reg. No. 117129) GMP status Remarks of the Evaluator Target species: Livestock, poultry Decision: Approved. Moreover, Registration Board advised the applicant to clearly mentic specific target species on label. 430. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength EAY-TNQ-UE9U dated 12-03-2024 Rs 30,000/- dated 07-03-2024 (Slip No. 16241534402) Antibiotic Form 5 Form 5 As per innovator's Specifications 30ml, 50ml, 100ml, 120ml, 2500ml, 1000ml, 1000ml, 2500ml, 200ml, 2500ml, 1000ml, 2500ml, 1000ml, 2500ml, 200ml,			
O7-03-2024 (Slip No. 16241534402) Pharmacological Group		Tracking ID data & for	
Pharmacological Group Type of Form Form 5 Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved. Moreover, Registration Board advised the applicant to clearly mentic specific target species on label. 430. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength As per innovator's Specifications As per innovator's Specifications As per innovator's Specifications As per innovator's Specifications How Doml, 120ml, 250ml, 500ml, 1000ml, 1000ml, 25000ml, 1000ml, 25000ml, 25000ml, 25000ml, 25000ml, 25000ml, 25000ml, 2500ml, 1000ml, 25000ml, 25000ml, 2500ml, 1000ml, 25000ml, 25000ml, 250ml, 1000ml, 25000ml, 250ml, 1000ml, 25000ml, 25000ml, 250ml, 200ml, 200ml, 25000ml, 250ml, 200ml, 200ml, 25000ml, 2500ml, 1000ml, 25000ml, 2500ml, 250ml, 200ml, 2500ml, 200ml, 2500ml, 200ml, 25000ml, 2500ml, 200ml, 2500ml, 2500ml, 2500ml, 200ml, 2500ml, 2500		Tracking ID, date & fee	
Type of Form Finished product Specification Pack size & Demanded Office Specification Pack size & Demanded Office Specification Pack size & Demanded Office Specification Office Specification Pack size & Demanded Office Specification Office		Di li la	
Finished product Specification Pack size & Demanded 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 500ml, 1000ml, 2500ml, 5000ml, 2500ml; Decontrolled Me-too status Entri SS Oral Liquid of M/s. Suave Pharmaceuticals I Ltd., Khurianwala, Faisalabad (Reg. No. 117129) GMP status Remarks of the Evaluator Target species: Livestock, poultry Decision: Approved. Moreover, Registration Board advised the applicant to clearly mentic specific target species on label. 430. Name and address of manufacturer / Applicant Applicant Brand Name +Dosage Form + Strength Flornix-10 Oral Liquid			
Pack size & Demanded 2500ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 25000ml; Decontrolled Me-too status Entri SS Oral Liquid of M/s. Suave Pharmaceuticals Entri SS Oral Liquid Oral Liquid Entri SS Oral Liquid Strength National Industrial Zone, Rawat. Flornix-10 Oral Liquid		- V 1	
2500ml, 5000ml, 25000ml; Decontrolled Me-too status			
Ltd., Khurianwala, Faisalabad (Reg. No. 117129) GMP status Remarks of the Evaluator Decision: Approved. Moreover, Registration Board advised the applicant to clearly mentices specific target species on label. 430. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Ltd., Khurianwala, Faisalabad (Reg. No. 117129) New DML Target species: Livestock, poultry M/s Pharmonix Pharmaceuticals, Plot 28, Street SS National Industrial Zone, Rawat. Flornix-10 Oral Liquid		Pack size & Demanded	2500ml, 5000ml, 25000ml; Decontrolled
GMP status Remarks of the Evaluator Target species: Livestock, poultry Decision: Approved. Moreover, Registration Board advised the applicant to clearly mentic specific target species on label. 430. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength New DML Target species: Livestock, poultry M/s Pharmonix Pharmaceuticals, Plot 28, Street SS National Industrial Zone, Rawat. Flornix-10 Oral Liquid		Me-too status	
Remarks of the Evaluator Target species: Livestock, poultry Decision: Approved. Moreover, Registration Board advised the applicant to clearly mentic specific target species on label. 430. Name and address of manufacturer / Applicant National Industrial Zone, Rawat. Brand Name +Dosage Form + Strength Target species: Livestock, poultry M/s Pharmonix Pharmaceuticals, Plot 28, Street SS National Industrial Zone, Rawat. Flornix-10 Oral Liquid		CMD	
Livestock, poultry Decision: Approved. Moreover, Registration Board advised the applicant to clearly mentices specific target species on label. 430. Name and address of manufacturer / Applicant National Industrial Zone, Rawat. Brand Name +Dosage Form + Flornix-10 Oral Liquid Strength			
Decision: Approved. Moreover, Registration Board advised the applicant to clearly mentices specific target species on label. 430. Name and address of manufacturer / Applicant National Industrial Zone, Rawat. Brand Name +Dosage Form + Flornix-10 Oral Liquid Strength		Remarks of the Evaluator	
Applicant M/s Pharmonix Pharmaceuticals, Plot 28, Street SS			* •
Applicant National Industrial Zone, Rawat. Brand Name +Dosage Form + Flornix-10 Oral Liquid Strength	120	Name and address of manufacturar /	M/c Pharmonix Pharmacouticals Plot 28 Street SS 2
Brand Name +Dosage Form + Flornix-10 Oral Liquid Strength	430.		
Strength		**	
			Flornix-10 Oral Liquid
Composition Each ml contains:		Composition	Each ml contains:
Florfenicol100mg		_	Florfenicol100mg
		Tracking ID, date & fee	AAW-2R8-RH4J dated 12-03-2024 Rs 30,000/- dated
07-03-2024 (Slip No. 20151804271)		, , , , , , , , , , , , , , , , , , , ,	
Pharmacological Group Antibiotic		Pharmacological Group	*
Type of Form Form 5			
Finished product Specification As per innovator's Specifications			
Pack size & Demanded 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml,			
2500ml, 500ml, 25000ml; Decontrolled		Tack Size & Demanded	
		Ma too status	
		Wie-too status	Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118543)
GMP status New DML		GMP status	
Remarks of the Evaluator Target species:			
Remarks of the Evaluator Poultry		Kemarks of the Evaluator	
Decision: Approved.		Decision: Approved	1 contag
	431		M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,
Applicant National Industrial Zone, Rawat.	731.		

	Brand Name +Dosage Form + Strength	Flornix-23 Oral Liquid
	Composition	Each ml contains:
	Composition	Florfenicol230mg
	Tracking ID, date & fee	978-JT9-233Z dated 12-03-2024 Rs 30,000/- dated 07-
	Trucking 1D, date & rec	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 /	M/s Pharmonix Pharmaceuticals, Plot 28, Street SS-2,
	Applicant	National Industrial Zone, Rawat.
	Brand Name +Dosage Form +	Til Nix Oral Liquid
	Strength	
	Composition	Each ml contains:
		Tilmicosin as Phosphate250mg
	Tracking ID, date & fee	GZJ-L1G-NT35 dated 12-03-2024 Rs 30,000/- dated 07-
	71	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)
	GI (D)	Ltd.,23 Multan (Reg. No.118612)
	GMP status	New DML
	Remarks of the Evaluator	Target species:
	D	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 Liqu	uid (Veterinary) Section	(New)		
	(10	Products/ 10 Molecules)			
433.	Name and address of manufacturer Applicant	/ M/s Medpharm Re Lahore	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore		
	Brand Name +Dosage Form + Strength	AR EC Med Super	AR EC Med Super oral solution		
Composition		Each ml contains:	Each ml contains:		
		Enrofloxacin	Enrofloxacin200mg		
		Colistin Sulphate	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	Antimicrobial		
	Type of Form	Form 5	Form 5		
	Finished product Specification	Manufacturer's Spe	Manufacturer's Specifications		
	Pack size & Demanded	1000ml and 5000m	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	New Section		
	Remarks of the Evaluator	Target species:			
		Calves, poultry	Calves, poultry		
		Shortcomings:	Shortcomings:		
			Rs.7500/- for correction in finished ions before issuance of registration		
	Decision: Approved. Firm shall submit Rs.7500/- for correction in finished pr specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 t issuance of registration letter.				
434.	Name and address of manufacturer Applicant	/ M/s Medpharm Re Lahore	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore		
	Brand Name +Dosage Form + Strength	Floramed Plus oral	Floramed Plus oral solution		
	Composition	Each 100ml contain	Each 100ml contains:		
		Florfenicol	Florfenicol23gm		

		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.
435.		
433.	Applicant	I M/s Medpharm Research Lab 28 Km Ferozpur Road I
	rppheant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	
	Brand Name +Dosage Form +	Lahore
	Brand Name +Dosage Form + Strength	AR Floramed-23 oral solution
	Brand Name +Dosage Form + Strength	Lahore AR Floramed-23 oral solution Each ml contains:
	Brand Name +Dosage Form + Strength Composition	Lahore AR Floramed-23 oral solution Each ml contains: Florfenicol
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee	Lahore AR Floramed-23 oral solution Each ml contains: Florfenicol
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group	Lahore AR Floramed-23 oral solution Each ml contains: Florfenicol
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form	Lahore AR Floramed-23 oral solution Each ml contains: Florfenicol
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification	Lahore AR Floramed-23 oral solution Each ml contains: Florfenicol
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	Lahore AR Floramed-23 oral solution Each ml contains: Florfenicol

	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.
	specifications as per notification	ibmit Rs.7500/- for correction in finished product No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before ver, Registration Board advised the applicant to clearly el.
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 Phosphate250mg
	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.
		abmit Rs.7500/- for correction in finished product No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before
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
	Minutes of 335 th meeting of Registr	ation Board (25 th April, 2024) 974

	Composition	Each ml contains:
		Bromhexine HCl50mg
	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.
438.		
438.	issuance of registration letter. Name and address of manufacturer /	No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before M/s Medpharm Research Lab, 28 Km Ferozpur Road
438.	issuance of registration letter. Name and address of manufacturer / Applicant	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
438.	issuance of registration letter. Name and address of manufacturer /	M/s Medpharm Research Lab, 28 Km Ferozpur Road
438.	issuance of registration letter. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore
438.	issuance of registration letter. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore E Med-10 oral solution
438.	issuance of registration letter. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore E Med-10 oral solution Each ml contains:
438.	issuance of registration letter. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore E Med-10 oral solution Each ml contains: Enrofloxacin
438.	issuance of registration letter. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore E Med-10 oral solution Each ml contains: Enrofloxacin
438.	issuance of registration letter. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore E Med-10 oral solution Each ml contains: Enrofloxacin
438.	issuance of registration letter. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore E Med-10 oral solution Each ml contains: Enrofloxacin
438.	issuance of registration letter. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore E Med-10 oral solution Each ml contains: Enrofloxacin
438.	issuance of registration letter. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore E Med-10 oral solution Each ml contains: Enrofloxacin
438.	issuance of registration letter. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	M/s Medpharm Research Lab, 28 Km Ferozpur Road Lahore E Med-10 oral solution Each ml contains: Enrofloxacin

		Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
		ubmit Rs.7500/- for correction in finished product No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before
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.
	_ = =	ubmit Rs.7500/- for correction in finished product No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before
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:
		Enrofloxacin75mg
		Sulfamethoxypyridazine75mg

		Sulfamethazine50mg
		Trimethoprim25mg
	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.
445	specifications as per notification issuance of registration letter.	No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before
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.
		ibmit Rs.7500/- for correction in finished product No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before
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 ronly.	regarding intended use in specifically cows and mares
	Oral Powder (Veterinary) Section (New)
	(10 Prod	lucts/ 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
	Tunding Id data 9. for	XDM-ZES-E692 dated 04-03-2024 Rs 30,000/- dated
	Tracking Id, date & fee	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.
	label claim in line with reference notification No.F.7-11/2012-B&A/DR	mit Rs.30,000/- for pre-approval change/correction in product and finished product specifications as per AP dated 07-05-2021 before issuance of registration advised the applicant to clearly mention specific target
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 C5gm
		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, e	fficacy and quality parameters.
445.	Name and address of manufacturer /	M/s Medpharm Research Lab, 28 Km Ferozpur Road
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	AR Nfcole oral powder
	Composition	Each gram contains:
		Neomycin Sulphate 150mg
		Florfenicol
		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.
		ibmit Rs.7500/- for correction in finished product No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before
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.
		ubmit Rs.7500/- for correction in finished product No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before
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 Sulphate70mg

	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.
	= =	abmit Rs.7500/- for correction in finished product No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before
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.
		abmit Rs.7500/- for correction in finished product No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before
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:
		Furosemide20gm
		Sodium Chloride35gm
		Potassium Chloride400mg
		Magnesium Chloride35gm
		Calcium Carbonate45gm
		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 / M/s Medpharm Research Lab, 28 Km Ferozpur Road **Applicant** Brand Name +Dosage Form + AR Fahsfo-Med Oral Powder Strength Composition Each Kg contains: Fosfomycin Calcium 200gm Tylosin Tartrate 100gm Fructose 180gm Sodium Phosphate 150gm Magnesium Sulphate 100gm Y1H-HVH-MEGR dated 03-03-2024 Rs 30,000/- dated Tracking Id, date & fee 28-02-2024 (Slip No. 2734826973) Pharmacological Group Antibiotic Type of Form Form 5 Manufacturer's Specifications Finished product Specification 500gm, 1000gm, and 5000gm; Decontrolled Pack size & Demanded Fosiril Powder of M/s Mallard Pharmaceuticals (Pvt) Me-too status 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 / M/s Medpharm Research Lab, 28 Km Ferozpur Road **Applicant** Lahore Brand Name +Dosage Form + AR Empro-Med Oral powder Strength 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.
	_ = =	ibmit Rs.7500/- for correction in finished product No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before
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)

	(=>1104	dets/ 10 Moretales)
453.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APRO-EN-10 Injection 100ml
	Strength	
	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 /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
454.		Bypass, Faisalabad.
	Applicant Brand Name +Dosage Form +	APRO-EN-10 Injection 10ml
	Strength	AFRO-EN-10 injection 10iiii
	Composition	Each ml contains:
	Composition	Enrofloxacin
	Tracking Id, date & fee	9QZ-TLN-W5H8 dated 28-02-2024 Rs 30,000/- dated
	Trucking fu, dute to fee	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)
	Nie too status	Ltd., Islamabad (Reg. No. 117226)
	GMP status	New Section
	Remarks of the Evaluator	Tien bedien
	Decision: Approved.	
455.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
100.	Applicant Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APRO-EN-20 Injection 100ml
	Strength	J. T. J. T. J. T.
	Composition	Each ml contains:
		Enrofloxacin200mg
	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 /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APRO-EN-20 Injection 10ml
	Strength	
	Composition	Each ml contains:
		Enrofloxacin
	Tracking Id, date & fee	QH3-GSD-QPTN dated 01-03-2024 Rs 30,000/- dated
	N 1 ' 1 C	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)
	GMP status	Ltd., Islamabad (Reg. No. 117223) New Section
	Remarks of the Evaluator	New Section
457.	Decision: Approved. Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
43/.	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APRO-EN-5 Injection 100ml
	Strength	AFRO-EN-5 Injection foolin
<u></u>	Buchgui	

	Commonition	Fool and contained
	Composition	Each ml contains:
	TD 1: 11 1 0 C	Enrofloxacin
	Tracking Id, date & fee	DU3-9NX-RQWM dated 23-02-2024 Rs 30,000/- dated
	Di li la	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 /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAFEN Injection 50ml
	Strength	111 21 11 21 1 11 1 1 1 1 1 1 1 1 1 1 1
	Composition	Each ml contains:
	Composition	Florfenicol
	Tracking Id, date & fee	EXP-RQR-9XT3 dated 23-02-2024 Rs 30,000/- dated
	Tracking id, date & ice	22-02-2024 (Slip No. 14477352)
	Pharmacological Group	Antibiotic
		Form 5
	Type of Form	
	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.,
	C) D	Karachi. (Reg. No. 043554)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
459.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAFEN Injection 10ml
	Strength	
	Composition	Each ml contains:
		Florfenicol30mg
	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
	B 1 1 0 B 1 1	10 1 D + 11 1
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd.,
		Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd.,
	Me-too status	Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 043554)
	Me-too status GMP status Remarks of the Evaluator	Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 043554)
460.	Me-too status GMP status Remarks of the Evaluator Decision: Approved.	Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 043554) New Section
460.	Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer /	Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 043554) New Section M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
460.	Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer / Applicant	Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 043554) New Section M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
460.	Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 043554) New Section M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
460.	Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 043554) New Section M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFEN-30 Injection 50ml
460.	Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 043554) New Section M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFEN-30 Injection 50ml Each ml contains:
460.	Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 043554) New Section M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFEN-30 Injection 50ml Each ml contains: Florfenicol
460.	Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Naflor Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 043554) New Section M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFEN-30 Injection 50ml Each ml contains:

	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,
	CMD status	Islamabad. (Reg. No. 118566)
	GMP status Remarks of the Evaluator	New Section
	Decision: Approved.	
461.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
701.	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAFEN-30 Injection 10ml
	Strength	AT LATE LIV-50 injection form
	Composition	Each ml contains:
		Florfenicol
	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 /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Colin-S Injection 100ml
	Strength	
	Composition	Each ml contains:
		Spiramycin Adipate 125 mg
		Lincomycin HCl75 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
	Designation Am 1 Dr 1 P 2	product before issuance of registration letter.
	1	mit Rs.30,000/- for pre-approval change/correction in
		roduct as per notification No.F.7-11/2012-B&A/DRAP
463.	dated 07-05-2021 before issuance of r Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
403.		
	Applicant Brand Name +Dosage Form +	Bypass, Faisalabad. Colin-S Injection 50ml
	Strength	Comi-s injection John
	Composition	Each ml contains:
	Composition	Spiramycin Adipate 125 mg
		Lincomycin HCl75 mg
		2 moonijom riemaanin 10 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,
	112 to 5 5 111 12 1	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 sub-	mit Rs.30,000/- for pre-approval change/correction in
		roduct as per notification No.F.7-11/2012-B&A/DRAP
	dated 07-05-2021 before issuance of re	
464.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Colin-S Injection 10ml
	Strength	
	Composition	Each ml contains:
		Spiramycin Adipate 125 mg
		Lincomycin HCl75 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
	D	product before issuance of registration letter.
		mit Rs.30,000/- for pre-approval change/correction in
		roduct as per notification No.F.7-11/2012-B&A/DRAP
465	dated 07-05-2021 before issuance of relation Name and address of manufacturer /	
465.	Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form +	Aplagent injection 100ml
	Strength	Apragent injection roomi
	Composition	Each ml contains:
	Composition	Gentamycin as sulphate50mg
		Tylosin as Tartrate100mg
	Tracking Id, date & fee	6AX-M8E-LJHS dated 24-02-2024 Rs 30,000/- dated
	Tracking id, date & rec	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,
	1.10 100 51111115	Lahore. (Reg. No. 118492)
	GMP status	New Section
	Remarks of the Evaluator	7.0
		1

	Decision: Approved.	
466.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Aplagent injection 50ml
	Strength	
	Composition	Each ml contains:
		Gentamycin as sulphate50mg
		Tylosin as Tartrate100mg
	Tracking Id, date & fee	89E-DAH-1Q4M dated 28-02-2024 Rs 30,000/- dated
	N 1 1 C	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 /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Aplagent injection 10ml
	Strength	
	Composition	Each ml contains:
		Gentamycin as sulphate50mg
		Tylosin as Tartrate100mg
	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 /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Aplaco-Cin Injection 50ml
	Strength	P 1 1 4
	Composition	Each ml contains:
		Lincomycin (as HCl)50mg
	Translation III days 0 for	Spectinomycin (as HCl)100mg
	Tracking Id, date & fee	SEZ-LX2-H57D dated 24-02-2024 Rs 30,000/- dated
	Dharmacalagical Group	22-02-2024 (Slip No. 2145672126) Antibiotic
	Pharmacological Group Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	As per innovator's Specifications 50ml; Decontrolled
	Me-too status	Stalin Injection of M/s Mylab (Pvt) Ltd,
	CMD status	Bahawalpur. (Reg. No. 101463) New Section
	GMP status Remarks of the Evaluator	New Section
	Decision: Approved.	

160	Name and address of manufacturer /	M/a Anthy Dharmacouticals 5 Vm Caracdha Daod
469.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant Page Page Farm	Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAOX-5 Injection 100ml
	Composition	Each ml contains:
	Composition	Oxytetracycline HCl50mg
	Tracking Id, date & fee	H64-5QY-9GBD dated 26-02-2024 Rs 30,000/- dated
	Tracking id, date & fee	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	As per innovator's Specifications 100ml; Decontrolled
	Me-too status	Oxyvetz 5% Injection of M/s Vetz Pharmaceuticals (Private) Limited Veta Sindh (Pag. No. 116804)
	CMD status	(Private) Limited., Kotri Sindh. (Reg. No.116894) New Section
	GMP status	New Section
	Remarks of the Evaluator	
450	Decision: Approved.	M/ A d Dl
470.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAOX-5 Injection 50ml
	Strength	Each ml contains:
	Composition	
	Tracking Id data & for	Oxytetracycline HCl50mg LUS-PSX-WN85 dated 26-02-2024 Rs 30,000/- dated
	Tracking Id, date & fee	
	Dhamma a alaai a l Cuana	27-02-2024 (Slip No. 53441311)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification Pack size & Demanded	As per innovator's Specifications
		50ml; Decontrolled
	Me-too status	A-Oxy-5% Injection of M/s Al-Habib Agencies,
	GMP status	Rawalpindi (Reg. No. 118485) New Section
		New Section
	Remarks of the Evaluator	
451	Decision: Approved.	M/- And- Discussed 1- 5 V. Consults Deed
471.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAOX-10 Injection 100ml
	Strength	Each ml contains:
	Composition	
	Tracking Id, date & fee	Oxytetracycline as HCl100mg 3ZM-TGS-2M9B dated 26-02-2024 Rs 30,000/- dated
	Tracking id, date & fee	22-02-2024 (Slip No. 362596065)
	Pharmacological Group	Antibiotic Antibiotic
		Form 5
	Type of Form Finished product Specification	
	Finished product Specification Pack size & Demanded	USP Specifications 100ml; Decontrolled
		,
	Me-too status	Oxyriq-10 Injection of M/s Baariq Pharmaceuticals,
	CMD status	Lahore (Reg. No. 087130) New Section
	GMP status	New Section
	Remarks of the Evaluator	
472	Decision: Approved.	M/a Anthu Dhamacautical E.V. G
472.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAOX-10 Injection 50ml
	Strength	

	Composition	Each ml contains:
	Composition	Oxytetracycline as HCl100mg
	Tracking Id, date & fee	XP2-647-5PB3 dated 01-03-2024 Rs 30,000/- dated 27-
	Trucking in, dute to rec	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,
	Me-too status	
	CMD	Lahore (Reg. No. 087129)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
473.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAOX-20 Injection 100ml
	Strength	
	Composition	Each ml contains:
		Oxytetracycline HCl200mg
	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,
	Wie-too status	Rawalpindi (Reg. No. 118486)
	GMP status	New Section
	Remarks of the Evaluator	New Section
	Decision: Approved.	
474.	Name and address of manufacturer /	M/a Antly Dharmacouticals 5 Km Sargadha Dood
4/4.		M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant Page 4 Page 4	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAOX-20 LA Injection 100ml
	Strength	Fact. 100ml acatalana
	Composition	Each 100ml contains:
		Oxytetracycline Base20gm
	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 /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
","	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAFLOX Injection 50ml
	_	AI LAI LOA IIIJEUIOII JUIII
	Strength	Each ml contains:
1	Composition	Each the Contains:
	•	Ovvetetmosvalina 200
		Oxytetracycline300 mg Flunixin Meglumine20 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 sub-	mit Rs.30,000/- for pre-approval change/correction in
		roduct as per notification No.F.7-11/2012-B&A/DRAP
	dated 07-05-2021 before issuance of re	
476.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
170.	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Ketostrep LA Injection 100ml
	Strength	Retostrep LA injection Toolin
	Composition	Each ml contains:
	Composition	Oxytetracycline as HCl200mg
	Totalina II 1-4- 0 for	Ketoprofen30mg
	Tracking Id, date & fee	P6S-L4W-ZBWZ dated 26-02-2024 Rs 30,000/- dated
	Di li la	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, et	fficacy and quality parameters.
477.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Ketostrep LA Injection 20ml
	Strength	
	Composition	Each ml contains:
		Oxytetracycline as HCl200mg
		Ketoprofen30mg
	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
	NIC-too status	(Pvt) Ltd., Lahore (Reg. No. 071091)
	GMP status	New Section
		INEW SECTION
	Remarks of the Evaluator	
		committee on Veterinary Drugs regarding therapeutic
4=0	requirement keeping in view safety, el	
478.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.

	Brand Name +Dosage Form +	Ketostrep LA Injection 50ml
	Strength	
	Composition	Each ml contains:
		Oxytetracycline as HCl200mg
		Ketoprofen30mg
	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,
	112 000 500000	Rawalpindi. (Reg. No. 111328)
	GMP status	New Section
	Remarks of the Evaluator	The Beetion
		-committee on Veterinary Drugs regarding therapeutic
	requirement keeping in view safety,	
479.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
4//.	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLA-SDD Injection 100ml
	Strength	Al LA-SDD Injection roomi
	Composition	Each ml contains:
	Composition	Sulfadimidine Sodium33.33%
	Treating Id data & for	58N-WNY-3HHD dated 26-02-2024 Rs 30,000/- dated
	Tracking Id, date & fee	
	Discourse 1 - 2 - 1 Corres	22-02-2024 (Slip No. 97347217464) Antibiotic
	Pharmacological Group	Form 5
	Type of Form	
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Sulpha DM Injection of M/s D-Maarson
	C) E	Pharmaceuticals, Rawat, Islamabad. (Reg. No. 078342)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Approved.	
480.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	ENBROX Injection 50ml
	Strength	
	Composition	Each ml contains:
		Enrofloxacin10%
		Bromhexine0.5%
	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.

		it Rs.30,000/- for pre-approval change/correction in label as per notification No.F.7-11/2012-B&A/DRAP dated 07-on letter.
481.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
1017	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	ENBROX Injection 100ml
	Strength	
	Composition	Each ml contains:
		Enrofloxacin10%
		Bromhexine0.5%
	Tracking Id, date & fee	MWH-J8G-VHH9 dated 01-03-2024 Rs 30,000/- dated
	Tracking ia, date & ice	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.
402	(22 Pro	id) (Veterinary) Section (New) ducts/ 08 Molecules)
482.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Rypace Faicalahad
		Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APIPRED Injection 50ml
	Brand Name +Dosage Form +	
	Brand Name +Dosage Form + Strength	APIPRED Injection 50ml
	Brand Name +Dosage Form + Strength	APIPRED Injection 50ml Each 100ml contains:
	Brand Name +Dosage Form + Strength	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm
	Brand Name +Dosage Form + Strength Composition	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469)
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115)
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115) New Section
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115) New Section Target species:
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115) New Section Target species: Cattle, horse, sheep, dogs, cats
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115) New Section Target species: Cattle, horse, sheep, dogs, cats Shortcomings:
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115) New Section Target species: Cattle, horse, sheep, dogs, cats
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for following:	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115) New Section Target species: Cattle, horse, sheep, dogs, cats Shortcomings: State role of Creatinine mentioned in master formula.
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for following: • review of Sub-committee on Vete	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115) New Section Target species: Cattle, horse, sheep, dogs, cats Shortcomings: State role of Creatinine mentioned in master formula.
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for following: • review of Sub-committee on Vete in view safety, efficacy and quality	Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115) New Section Target species: Cattle, horse, sheep, dogs, cats Shortcomings: State role of Creatinine mentioned in master formula.
	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for following: • review of Sub-committee on Vete in view safety, efficacy and qualiter of the composition of the compositio	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115) New Section Target species: Cattle, horse, sheep, dogs, cats Shortcomings: State role of Creatinine mentioned in master formula. rinary Drugs regarding therapeutic requirement keeping by parameters. master formula.
483.	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for following: • review of Sub-committee on Vete in view safety, efficacy and qualit • role of Creatinine mentioned in r Name and address of manufacturer /	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115) New Section Target species: Cattle, horse, sheep, dogs, cats Shortcomings: State role of Creatinine mentioned in master formula. rinary Drugs regarding therapeutic requirement keeping ty parameters. master formula. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
483.	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for following: • review of Sub-committee on Vete in view safety, efficacy and qualit • role of Creatinine mentioned in r Name and address of manufacturer / Applicant	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115) New Section Target species: Cattle, horse, sheep, dogs, cats Shortcomings: State role of Creatinine mentioned in master formula. rinary Drugs regarding therapeutic requirement keeping ty parameters. master formula. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
483.	Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for following: • review of Sub-committee on Vete in view safety, efficacy and qualit • role of Creatinine mentioned in r Name and address of manufacturer /	APIPRED Injection 50ml Each 100ml contains: Prednisolone as Acetate0.75gm Dexamethasone as Sodium Phosphate0.25gm XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469) Adrenocortical steroid anti-inflammatory drug Form 5 As per innovator's Specifications 50ml; Decontrolled Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115) New Section Target species: Cattle, horse, sheep, dogs, cats Shortcomings: State role of Creatinine mentioned in master formula. rinary Drugs regarding therapeutic requirement keeping ty parameters. master formula. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road

		E 1 100 1	
	Composition	Each 100ml contains:	
		Prednisolone as Acetate0.75gm	
	T 1: 11 1 0 C	Dexamethasone as Sodium Phosphate0.25gm	
	Tracking Id, date & fee	DR8-LBM-E7P6 dated 28-02-2024 Rs 30,000/- dated	
	Discussion of Control	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 Vete	rinary Drugs regarding therapeutic requirement keeping	
	in view safety, efficacy and quali		
	• role of Creatinine mentioned in 1	master formula.	
484.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road	
	Applicant	Bypass, Faisalabad.	
	Brand Name +Dosage Form +	Predphen-14 Injection 50ml	
	Strength		
	Composition	Each ml contains:	
		Prednisolone10mg	
		Chlorpheniramine Maleate4 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 quali		
		mula since Creatinine is mentioned.	
		pel claim in line with reference product as prescribed vide	
	S.R.O. 496(I)/2023 dated 17-04-2	<u> </u>	
485.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road	
100.	Applicant	Bypass, Faisalabad.	
	Brand Name +Dosage Form +	Predphen-14 Injection 10ml	
	Strength	1100phon 1 i injection 10mm	
	Composition	Each ml contains:	
	Composition	Prednisolone10mg	
<u> </u>	Minutes of 225th months and Daniel	•	

		Chlorpheniramine Maleate4 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:
	Remarks of the Evaluator	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:	5.R.O. 470(1)/2023 dated 17-04-2023.
	9	in any Duyga vaganding the vancutie vaguinement bearing
	in view safety, efficacy and qualit	inary Drugs regarding therapeutic requirement keeping
	_ · · · · · · · · · · · · · · · · · · ·	nula since Creatinine is mentioned.
	S.R.O. 496(I)/2023 dated 17-04-20	el claim in line with reference product as prescribed vide
486.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
700.	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Predphen-40 Injection 50ml
	Strength	Treaphen to injection 50mi
	Composition	Each ml contains:
	•	Prednisolone Acetate25mg
		Chlorpheniramine Maleate10 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:	
		inary Drugs regarding therapeutic requirement keeping
	in view safety, efficacy and quality	
405	• Role of Creatinine mentioned in r	
487.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant Prond Name Deceme Form	Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Predphen-40 Injection 10ml
	Composition	Each ml contains:
	Composition	Prednisolone Acetate 25mg

Prednisolone Acetate......25mg Chlorpheniramine Maleate.....10 mg

	T. 11 11 0 0	001/ 011/ 1/200 1 - 101/02/024 B
	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:	
		inary Drugs regarding therapeutic requirement keeping
	in view safety, efficacy and quality	parameters.
	Role of Creatinine mentioned in n	
488.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAPRED-10 Injection 50ml
	Strength	
	Composition	Each ml contains:
		Prednisolone Acetate10mg
	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,
	GI (D)	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:	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	
		ed product specifications before issuance of registration
	letter.	ed product specifications before issuance of registration
489.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
402.	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAPRED-10 Injection 10ml
	Strength	AI LAI KLD-10 Injection 10mi
	Composition	Each ml contains:
	Composition	Prednisolone Acetate10mg
	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
<u> </u>	Minutes of 225th mosting of Pagistr	

	Ma too status	CD Duad Injection of M/o Chand Dhamas (Dut) I td
	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:	issuance of registration letter.
		inary Drugs regarding therapeutic requirement keeping
	in view safety, efficacy and quality	
		ed product specifications before issuance of registration
	letter.	ed product specifications serore issuance of registration
490.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
470.	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Aplapred-25 Injection 50ml
	Strength	Apiapieu-25 injection 50iiii
	Composition	Each ml contains:
	o o o o o o o o o o o o o o o o o o o	Prednisolone25mg
	Tracking Id, date & fee	QE2-4JD-PMP6 dated 28-02-2024 Rs 30,000/- dated 24-
	True ming ray auto et rot	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.
	THE too status	(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, e	
491.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Aplapred-25 Injection 10ml
	Strength	
	Composition	Each ml contains:
		Prednisolone25mg
	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, e	
492.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.

0		
	Brand Name +Dosage Form + Strength	Aplapred-25 Injection 100ml
	Composition	Each ml contains: Prednisolone25mg
	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, e	
493.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
1500	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Apthason-1 Injection 50ml
	Strength	
	Composition	Each ml contains:
	_	Dexamethasone as Sodium Phosphate1mg
	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, e	
494.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Apthason-2 Injection 50ml
	Strength	Each ml contains:
	Composition	Dexamethasone Sodium Phosphate eq to
		Dexamethasone Phosphate2mg
	Tracking Id, date & fee	Z8E-D71-TM28 dated 28-02-2024 Rs 30,000/- dated 24-
	Trucking id, date & fee	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:
		<u> </u>

		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, e	• 0 0 •
495.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
493.	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Apthason-4 Injection 50ml
	Strength	Aptilason-4 injection 30iiii
	Composition	Each ml contains:
	Composition	Dexamethasone Sodium Phosphate eq to
		Dexamethasone base4mg
	Tracking Id, date & fee	VJN-J5R-3EA1 dated 28-02-2024 Rs 30,000/- dated 24-
	Tracking id, date & fee	02-2024 (Slip No. 8424685840)
	Pharmacological Group	Steroid
	Pharmacological Group	Form 5
	Type of Form	
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Dexamethasone Injection of M/s Amros Pharm Karachi
	C) E	(Reg. No. 020100)
	GMP status	New Section
	Remarks of the Evaluator	Target species:
		Horse, sheep goats, dogs, cats
		-committee on Veterinary Drugs regarding therapeutic
	requirement keeping in view safety, e	
496.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLA OTD Injection 50ml
	Strength	
	Composition	Each 100ml contains:
		Oxytetracycline15gm
		Tripelenamine HCl1gm
		Dexamethasone0.050gm
	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:
	Remarks of the Evaluator	Horse, cattle, sheep goats, dogs, cats
	Decision: Deferred for review of Sub	-committee on Veterinary Drugs regarding therapeutic
	requirement keeping in view safety, e	
497.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
427.	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	KENA-S Injection 100ml
	Strength	KENT-5 injection roomi
	Composition	Each ml contains:
	Composition	Kanamycin Sulphate50mg
		Colistin Sulphate100000 IU
		Neomycin Sulphate50mg Povemethogone 21 Phognhate Sodium Solt 0.5 mg
	Translation Id. days 0 for	Dexamethasone 21 Phosphate Sodium Salt0.5 mg
	Tracking Id, date & fee	DRA-A2S-DN9Z dated 28-02-2024 Rs 30,000/- dated
	Discussion 1 C	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	The House Section
		-committee on Veterinary Drugs regarding therapeutic
	requirement keeping in view safety, el	• • • • •
498.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
470.	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Typhendex-G Injection 50ml
	_	Typhendex-O injection 30iii
	Strength	Each ml contains:
	Composition	
		Thiamphenicol200mg
		Tylosin57.5mg
		Prednisolone as Acetate5mg
	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, e	fficacy and quality parameters and complete salt form
	of Tylosin.	
499.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Typhendex-G Injection 10ml
	Strength	Typhonom o injection form
	Composition	Each ml contains:
	Composition	Thiamphenicol200mg
		Tylosin57.5mg
		Prednisolone as Acetate5mg
	Tracking Id, date & fee	4ZA-VRV-J69N dated 01-03-2024 Rs 30,000/- dated
	Tracking id, date & fee	27-02-2024 (Slip No. 855673114)
	Dhamma a ala si a al Cuanu	
	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
		Speens sale rolling of Tyrosin

		b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and complete salt form
500.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Applicant Brand Name +Dosage Form + Strength	Tydogen Injection100ml
	Composition	Each 100ml contains:
		Tylosin Tartrate15gm
		Gentamycin Sulphate6gm
		Dexamethasone0.0265gm
		Chlorpheniramine0.750gm
	Tracking Id, date & fee	NX7-G19-DGBJ dated 28-02-2024 Rs 30,000/- dated
	DI 1 1 C	24-02-2024 (Slip No. 92478096714)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification Pack size & Demanded	As per innovator's Specifications
	Me-too status	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:
	Remarks of the Evaluator	Livestock, poultry
		Shortcomings:
		Firm shall submit fee Rs. 30,000/- for revision of label
		claim in line with reference product as prescribed vide
		claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of
501	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023.	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O.
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer /	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains:
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate15gm
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains:
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate15gm Gentamycin Sulphate6gm Dexamethasone
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate15gm Gentamycin Sulphate6gm Dexamethasone
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate15gm Gentamycin Sulphate6gm Dexamethasone6gm Chlorpheniramine0.750gm 6PV-J4N-EMNR dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 071348776314)
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate15gm Gentamycin Sulphate6gm Dexamethasone0.0265gm Chlorpheniramine0.750gm 6PV-J4N-EMNR dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 071348776314) Steroid and antimicrobial Form 5 As per innovator's Specifications
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate6gm Dexamethasone6gm Devamethasone0.0265gm Chlorpheniramine0.750gm 6PV-J4N-EMNR dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 071348776314) Steroid and antimicrobial Form 5 As per innovator's Specifications 10ml; Decontrolled Genta Combisone Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 046696) New Section
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate6gm Gentamycin Sulphate6gm Dexamethasone0.0265gm Chlorpheniramine0.750gm 6PV-J4N-EMNR dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 071348776314) Steroid and antimicrobial Form 5 As per innovator's Specifications 10ml; Decontrolled Genta Combisone Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 046696) New Section Target species:
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate
501.	requirement keeping in view safety, Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	S.R.O. 496(I)/2023 dated 17-04-2023. b-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 10ml Each 100ml contains: Tylosin Tartrate

	requirement keeping in view safety, e	p-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O.
502.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Tydogen Injection 50ml
	Strength	
	Composition	Each 100ml contains:
		Tylosin Tartrate15gm
		Gentamycin Sulphate6gm
		Dexamethasone0.0265gm
		Chlorpheniramine0.750gm
	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)
	G) (D)	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.
	Desigion: Deferred for review of Sub	committee on Veterinary Dungs resording thereneutic
	requirement keeping in view safety, e	o-committee on Veterinary Drugs regarding therapeutic efficacy and quality parameters and for submission of a in line with reference product as prescribed yide S.R.O.
	requirement keeping in view safety, 6 Rs. 30,000/- for revision of label claim	
503.	requirement keeping in view safety, 6 Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023.	efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O.
503.	requirement keeping in view safety, 6 Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer /	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
503.	requirement keeping in view safety, e Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
503.	requirement keeping in view safety, 6 Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer /	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate15gm Gentamycin Sulphate6gm Dexamethasone6gm Chlorpheniramine0.750gm
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate15gm Gentamycin Sulphate6gm Dexamethasone6gm Chlorpheniramine0.750gm ZU3-1UJ-WV4W dated 01-03-2024 Rs 30,000/- dated
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate15gm Gentamycin Sulphate6gm Dexamethasone6gm Chlorpheniramine0.750gm ZU3-1UJ-WV4W dated 01-03-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 915778667524)
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate15gm Gentamycin Sulphate6gm Dexamethasone0.0265gm Chlorpheniramine0.750gm ZU3-1UJ-WV4W dated 01-03-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 915778667524) Steroid and antimicrobial
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate15gm Gentamycin Sulphate6gm Dexamethasone0.0265gm Chlorpheniramine0.750gm ZU3-1UJ-WV4W dated 01-03-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 915778667524) Steroid and antimicrobial Form 5
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate
503.	requirement keeping in view safety, of Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	efficacy and quality parameters and for submission of a in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate6gm Gentamycin Sulphate6gm Dexamethasone0.0265gm Chlorpheniramine0.750gm ZU3-1UJ-WV4W dated 01-03-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 915778667524) Steroid and antimicrobial Form 5 As per innovator's Specifications 250ml; Decontrolled Genta Combisone Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 046696) New Section
503.	requirement keeping in view safety, et Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate15gm Gentamycin Sulphate6gm Dexamethasone0.0265gm Chlorpheniramine0.750gm ZU3-1UJ-WV4W dated 01-03-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 915778667524) Steroid and antimicrobial Form 5 As per innovator's Specifications 250ml; Decontrolled Genta Combisone Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 046696) New Section Target species:
503.	requirement keeping in view safety, of Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate
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503.	requirement keeping in view safety, of Rs. 30,000/- for revision of label claim 496(I)/2023 dated 17-04-2023. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	efficacy and quality parameters and for submission of in line with reference product as prescribed vide S.R.O. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Tydogen Injection 250ml Each 100ml contains: Tylosin Tartrate

•	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 manuf			
	•	llin) (Veterinary) Section (New)		
	`	oducts/ 10 Molecules)		
504.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road		
	Applicant	Bypass, Faisalabad.		
	Brand Name +Dosage Form +	DICANE Injection 50ml		
	Strength	Early and a surface of		
	Composition	Each ml contains:		
		Procaine Penicillin G200000 IU		
		Dihydrostreptomycin Sulfate250 mg Dexamethasone 1mg		
	Tracking Id, date & fee	2ME-JA3-8JMQ dated 28-02-2024 Rs 30,000/- dated		
	Tracking id, date & fee	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,		
	Wie-too status	Sargodha (Reg. No. 049533)		
	GMP status	New Section		
	Remarks of the Evaluator	Target species:		
	Remarks of the Evaration	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 /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road		
	Applicant	Bypass, Faisalabad.		
	Brand Name +Dosage Form +	AP-STREP-D Injection 50ml		
	Strength			
	Composition	Each ml contains:		
		Ampicillin Trihydrate100mg		
		Colistin Sulfate250000 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		
		o-committee on Veterinary Drugs regarding therapeutic		
	requirement keeping in view safety,			
506.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road		
	Applicant	Bypass, Faisalabad.		

	Brand Name +Dosage Form + Strength	APLAMOX-15 LA Injection 100ml
	Composition	Each ml contains: Amoxicillin As Trihydrate150 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:
	Decision: Approved.	Cattle, sheep, dogs, cats and poultry
507.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
307.	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAMOX-15 LA Injection 50ml
	Strength	AI LAWOA-13 LA INJECTION 30M
	Composition	Each ml contains:
	1	Amoxicillin As Trihydrate150 mg
	Tracking Id, date & fee	NJ4-Y46-31RA dated 29-02-2024 Rs 30,000/- dated 26-
	β a, a	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
	The too status	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 +	APLAMOX-20 LA Injection 50ml
	Strength	June
	Composition	Each ml contains:
		Amoxicillin As Trihydrate200 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:
	Kemarks of the Evaluator	Livestock and poultry
	Decision: Approved Moreover Peri	istration Board advised the applicant to clearly mention
	specific target species on label.	mentalist board advised the applicant to cicarry inclition
	1 specific anger species on lanci.	

509.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAMOX-20 LA Injection 100ml
	Strength	
	Composition	Each ml contains:
		Amoxicillin As Trihydrate200 mg
	Tracking Id, date & fee	D5Y-2RZ-L4LS dated 26-02-2024 Rs 30,000/- dated 23-
	71	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.
	CMD	119716)
	GMP status	New Section
	Remarks of the Evaluator	Target species: Livestock and poultry
	Dagisian: Approved Maragyar Pagis	stration Board advised the applicant to clearly mention
	specific target species on label.	stration board advised the applicant to clearly mention
510.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
310.	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAMOX-25 LA Injection 100ml
	Strength	In Brinion 25 Bir injection room
	Composition	Each ml contains:
	Composition	Amoxicillin Trihydrate250 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 Roard dispos	sed of the instant application since same formulation
		X-20 LA Injection 100ml vide tracking ID D5Y-2RZ-
	L4LS dated 26-02-2024 is approved in	
511.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLOSTIN Injection 100ml
	Strength	Jan 1
	Composition	Each ml contains:
	1	Amoxicillin as Trihydrate100mg
		Colistin Sulphate250000IU
	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

	True of Forms	E 5
	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, Regi	stration Board advised the applicant to clearly mention
	specific target species on label.	11
512.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
312.	Applicant Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLOSTIN Injection 50ml
	Strength	Al LOST IN Injection 30III
	Č	Each ml contains:
	Composition	
		Amoxicillin as Trihydrate100mg
	TD 11 11 0 C	Colistin Sulphate250000IU
	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:
	Remarks of the Evaluator	Livestock and poultry
	D: A	
	specific target species on label.	stration Board advised the applicant to clearly mention
513.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Aplacin Injection 100ml
	Strength	1 3
	Composition	Each ml contains:
		Amoxicillin Trihydrate150mg
		Gentamycin Sulfate eq to Gentamycin40mg
	Tracking Id, date & fee	485-R79-6H33 dated 27-02-2024 Rs 30,000/- dated 23-
	Tracking iu, date & ice	· · · · · · · · · · · · · · · · · · ·
	Discourse a sile of a 1 Course	02-2024 (Slip No. 734842424)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
		100ml; Decontrolled
	Pack size & Demanded	·
	Pack size & Demanded Me-too status	AMOVET-GT Injection of M/s Nawan Laboratories
		·
		AMOVET-GT Injection of M/s Nawan Laboratories
	Me-too status	AMOVET-GT Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi (Reg. No. 118398) New Section
	Me-too status GMP status	AMOVET-GT Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi (Reg. No. 118398) New Section Target species:
	Me-too status GMP status	AMOVET-GT Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi (Reg. No. 118398) New Section Target species: Cattle, buffalo, sheep, goat and poultry
	Me-too status GMP status	AMOVET-GT Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi (Reg. No. 118398) New Section Target species: Cattle, buffalo, sheep, goat and poultry Shortcomings:
	Me-too status GMP status	AMOVET-GT Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi (Reg. No. 118398) New Section Target species: Cattle, buffalo, sheep, goat and poultry Shortcomings: Firm shall submit Rs.30,000/- for pre-approval
	Me-too status GMP status	AMOVET-GT Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi (Reg. No. 118398) New Section 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
	Me-too status GMP status Remarks of the Evaluator	AMOVET-GT Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi (Reg. No. 118398) New Section 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.
	Me-too status GMP status Remarks of the Evaluator Decision: Approved. Firm shall sub	AMOVET-GT Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi (Reg. No. 118398) New Section 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. omit Rs.30,000/- for pre-approval change/correction in
	Me-too status GMP status Remarks of the Evaluator Decision: Approved. Firm shall sub	AMOVET-GT Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi (Reg. No. 118398) New Section 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. omit Rs.30,000/- for pre-approval change/correction in broduct as per notification No.F.7-11/2012-B&A/DRAP

514.	None and address of manufactures /	M/a Antley Dhammanuticala 5 V.m. Canadha Daad
514.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	Aplacin Injection 50ml
	Strength	
	Composition	Each ml contains:
		Amoxicillin Trihydrate150mg
		Gentamycin Sulfate eq to Gentamycin40mg
	Tracking Id, date & fee	A9X-Z7Q-SSP6 dated 28-02-2024 Rs 30,000/- dated 26-
	Tracking id, date & rec	
	N 1 : 1 C	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	t Rs.30,000/- for pre-approval change/correction in label
		s per notification No.F.7-11/2012-B&A/DRAP dated 07-
	05-2021 before issuance of registration	
F15		
515.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APS-LA Injection 50ml
	Strength	
	Composition	Each ml contains:
		Benzathin Penicillin G100000IU
		Procaine Penicillin G150000IU
		Dihydrostreptomycin Sulfate Base200mg
	Tracking Id, date & fee	5TP-NDG-UYJ9 dated 27-02-2024 Rs 30,000/- dated
	Tracking id, date & fee	23-02-2024 (Slip No. 03895556481)
	Discourse 1 - 1 - 1 Corres	
	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:
	Kemarks of the Evaluator	
	D	Cattle, horse, sheep, goat and poultry
	Decision: Approved.	1
516.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APS-LA 20ml Injection
	Strength	
	Composition	Each ml contains:
	r	Benzathin Penicillin G100000IU
		Procaine Penicillin G150000IU
	T 1: X1 1 . 0 . 0	Dihydrostreptomycin Sulfate Base200mg
	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.,
	Wie-too status	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 /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APS-LA 100ml Injection
	Strength	
	Composition	Each ml contains:
		Benzathin Penicillin G100000IU
		Procaine Penicillin G150000IU
		Dihydrostreptomycin Sulfate Base200mg
	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:
		9 2
		Cattle, horse, sheep, goat and poultry
518	Decision: Approved.	Cattle, horse, sheep, goat and poultry
518.	Decision: Approved. Name and address of manufacturer /	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
518.	Decision: Approved. Name and address of manufacturer / Applicant	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains:
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G200mg
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G200mg Dihydrostreptomycin250mg S45-HGR-57EM dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 344660534969) Penicillin antibiotic
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G200mg Dihydrostreptomycin250mg S45-HGR-57EM dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 344660534969) Penicillin antibiotic Form 5
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
518.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved.	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
518. 519.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer /	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer / Applicant	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G
	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Cattle, horse, sheep, goat and poultry M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. Strep-G 450 Injection 50ml Each ml contains: Procaine Penicillin G

	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 sub	omit Rs.7500/- for pre-approval change/correction in
		notification No.F.7-11/2012-B&A/DRAP dated 07-05-
520.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAMYCIN-15 Injection 100ml
	Composition	Each ml contains:
		Ampicillin Trihydrate150 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.
	label claim in line with reference pr	mit Rs.30,000/- for pre-approval change/correction in roduct as per notification No.F.7-11/2012-B&A/DRAP
	dated 07-05-2021 before issuance of re	
521.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAMYCIN-10 Injection 100ml
	Strength	
	Composition	Each ml contains: Ampicillin Trihydrate100 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 sub	mit Rs.30,000/- for pre-approval change/correction in
		roduct as per notification No.F.7-11/2012-B&A/DRAP
1 1	dated 07-05-2021 before issuance of re	<u>-</u>
522.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAMYCIN-20 Injection 100ml
	Strength	
	Composition	Each ml contains:
	•	Ampicillin Trihydrate200 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 sub	mit Rs.30,000/- for pre-approval change/correction in
	label claim in line with reference pr dated 07-05-2021 before issuance of re	roduct as per notification No.F.7-11/2012-B&A/DRAP egistration letter.
	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	CLAPEN 50ml Injection
	Strength	J
_	Composition	Each ml contains:
	•	Amoxicillin as Trihydrate140mg
		Clavulanic Acid35mg
	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
<u> </u>	Remarks of the Evaluator	Target Species:
		Livestock, dogs
	Decision: Approved. Moreover, Regist	tration Board advised the applicant to clearly mention
1 1	specific target species on label.	

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524.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form +	CLAPEN 20ml Injection
	Strength	OEI II EI (20111 Injection
	Composition	Each ml contains:
	Composition	Amoxicillin as Trihydrate140mg
		Clavulanic Acid35mg
	Tracking Id, date & fee	UP4-LAP-RS92 dated 29-02-2024 Rs 30,000/- dated 26-
	Tracking id, date & rec	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
	CMD	Pharmaceutica, Lahore. (Reg. No.102138 and 102139)
	GMP status	New Section
	Remarks of the Evaluator	Target Species:
	Davidson Assessed Manager David	Livestock, dogs
		stration Board advised the applicant to clearly mention
525.	specific target species on label. Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
525.		Bypass, Faisalabad.
	Applicant Brand Name +Dosage Form +	CLAPEN 100ml Injection
	Strength	CLAPEN TOOMI INJECTION
	Composition	Each ml contains:
	Composition	Amoxicillin as Trihydrate140mg
		Clavulanic Acid35mg
	Treating Id data & foo	NGH-R24-23GW dated 27-02-2024 Rs 30,000/- dated
	Tracking Id, date & fee	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,
	Wie-too status	Lahore. (Reg. No. 102139)
	GMP status	New Section
	Remarks of the Evaluator	Target Species:
	Remarks of the Evaluator	Livestock, dogs
	Decision: Approved Moreover Regis	stration Board advised the applicant to clearly mention
	specific target species on label.	stration board advised the applicant to clearly mention
526.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLAMCIL Injection 100ml
	Strength	J
	Composition	Each ml contains:
		Ampicillin as Trihydrate125mg
		Cloxacillin as Sodium125mg
	Tracking Id, date & fee	J35-N2Q-D4YP dated 27-02-2024 Rs 30,000/- dated 23-
	<i>6</i> .,	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
	110 100 Status	Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No.
		109193)
	1	,

	GMP status	New Section
	Remarks of the Evaluator	Target Species:
	Remarks of the Evaluator	Livestock, poultry
	Decision: Approved Margover P	Registration Board advised the applicant to clearly mention
	specific target species on label.	registration board advised the applicant to clearly mention
		neral) (Veterinary) Section (New)
		Products/ 10 Molecules)
527.	Name and address of manufacturer	
327.	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APCYNO-125 Injection 100ml
	Strength	THE THE 120 INJUSTION TOOMS
	Composition	Each ml contains:
	•	Cyanocobalamin125mcg
	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
	D	issuance of registration letter.
		submit Rs.7500/- for pre-approval change/correction in
	I timighed product apositiontions of	
	1 -	s per notification No.F.7-11/2012-B&A/DRAP dated 07-05-
528.	finished product specifications as 2021 before issuance of registration. Name and address of manufacturer.	on letter.
528.	2021 before issuance of registration Name and address of manufacturer.	hon letter. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
528.	Name and address of manufacturer Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
528.	Name and address of manufacturer Applicant Brand Name +Dosage Form +	hon letter. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
528.	Name and address of manufacturer Applicant Brand Name +Dosage Form + Strength	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
528.	Name and address of manufacturer Applicant Brand Name +Dosage Form +	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains:
528.	Name and address of manufacturer Applicant Brand Name +Dosage Form + Strength	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml
528.	Name and address of manufacturer Applicant Brand Name +Dosage Form + Strength Composition	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin250mcg
528.	Name and address of manufacturer Applicant Brand Name +Dosage Form + Strength Composition	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin250mcg Q25-BXZ-9P61 dated 27-02-2024 Rs 30,000/- dated 23-
528.	2021 before issuance of registration Name and address of manufacturer of Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin250mcg Q25-BXZ-9P61 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 27056099597)
528.	2021 before issuance of registration Name and address of manufacturer Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin250mcg Q25-BXZ-9P61 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 27056099597) Vitamin
528.	2021 before issuance of registratic Name and address of manufacturer Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin250mcg Q25-BXZ-9P61 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 27056099597) Vitamin Form 5
528.	2021 before issuance of registration Name and address of manufacturer of Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin250mcg Q25-BXZ-9P61 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 27056099597) Vitamin Form 5 As per innovator's Specifications
528.	2021 before issuance of registration Name and address of manufacturer of Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin250mcg Q25-BXZ-9P61 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 27056099597) Vitamin Form 5 As per innovator's Specifications 100ml; Decontrolled
528.	2021 before issuance of registration Name and address of manufacturer of Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin250mcg Q25-BXZ-9P61 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 27056099597) Vitamin Form 5 As per innovator's Specifications 100ml; Decontrolled Cormax Injection of M/s Nawan Laboratories (Pvt.) Ltd,
528.	Name and address of manufacturer Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin250mcg Q25-BXZ-9P61 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 27056099597) Vitamin Form 5 As per innovator's Specifications 100ml; Decontrolled Cormax Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 117157)
528.	2021 before issuance of registratic Name and address of manufacturer Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin250mcg Q25-BXZ-9P61 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 27056099597) Vitamin Form 5 As per innovator's Specifications 100ml; Decontrolled Cormax Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 117157) New Section Target Species: Sheep, goats, Dogs, cats, calves, foals, cattle, horses
528.	2021 before issuance of registratic Name and address of manufacturer Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin250mcg Q25-BXZ-9P61 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 27056099597) Vitamin Form 5 As per innovator's Specifications 100ml; Decontrolled Cormax Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 117157) New Section Target Species: Sheep, goats, Dogs, cats, calves, foals, cattle, horses Shortcomings:
528.	2021 before issuance of registratic Name and address of manufacturer Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin250mcg Q25-BXZ-9P61 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 27056099597) Vitamin Form 5 As per innovator's Specifications 100ml; Decontrolled Cormax Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 117157) New Section Target Species: Sheep, goats, Dogs, cats, calves, foals, cattle, horses Shortcomings: Official monograph of the applied formulation is
528.	2021 before issuance of registratic Name and address of manufacturer Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin
528.	2021 before issuance of registratic Name and address of manufacturer Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APCYNO-250 Injection 100ml Each ml contains: Cyanocobalamin250mcg Q25-BXZ-9P61 dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 27056099597) Vitamin Form 5 As per innovator's Specifications 100ml; Decontrolled Cormax Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 117157) New Section Target Species: Sheep, goats, Dogs, cats, calves, foals, cattle, horses Shortcomings: Official monograph of the applied formulation is

		omit Rs.7500/- for pre-approval change/correction in r notification No.F.7-11/2012-B&A/DRAP dated 07-05-etter.
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: Cyanocobalamin250mcg
	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.
		omit Rs.7500/- for pre-approval change/correction in notification No.F.7-11/2012-B&A/DRAP dated 07-05-etter.
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: Cyanocobalamin250mcg
	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)
	THE too status	Ltd., Lahore. (Reg. No.072692)
	GMP status	New Section
	Remarks of the Evaluator	Target Species:
	remarks of the Dyurumor	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 sub	
	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 /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
551.	Applicant Applicant	Bypass, Faisalabad.

	T	T . = =====
	Brand Name +Dosage Form + Strength	APCYNO-100 Injection 100ml
	Composition	Each ml contains:
		Cyanocobalamin1000mcg
	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.
		omit Rs.7500/- for pre-approval change/correction in
		notification No.F.7-11/2012-B&A/DRAP dated 07-05-
	2021 before issuance of registration le	
532.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLACAM-7.5 Injection 50ml
	Composition	Each ml contains:
	-	Meloxicam7.5mg
	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 sub	omit 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 le	
533.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLACAM-7.5 Injection 100ml
	Strength	
	Composition	Each ml contains:
		Meloxicam7.5mg
	Tracking Id, date & fee	71G-56E-LYUJ dated 01-03-2024 Rs 30,000/- dated 27-
	_	02-2024 (Slip No. 1805146621)

	Pharmacological Group	NSAID
		Form 5
	Type of Form	
	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.
		omit Rs.7500/- for pre-approval change/correction in
		notification No.F.7-11/2012-B&A/DRAP dated 07-05-
	2021 before issuance of registration le	tter.
534.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLACAM-10 Injection 20ml
	Strength	
	Composition	Each ml contains:
		Meloxicam10mg
	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 sub	omit Rs.7500/- for pre-approval change/correction in
		notification No.F.7-11/2012-B&A/DRAP dated 07-05-
	2021 before issuance of registration le	
535.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLACAM-10 Injection 100ml
	Strength	- · · · · · · · · · · · · · · · · · · ·
	Composition	Each ml contains:
	Composition	Meloxicam10mg
	Tracking Id, date & fee	AXB-5A5-TQZN dated 01-03-2024 Rs 30,000/- dated
	Tracking ra, date to rec	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	·
	ivic-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
	Design Assessed Figure 1 all and	issuance of registration letter.
		omit Rs.7500/- for pre-approval change/correction in
		notification No.F.7-11/2012-B&A/DRAP dated 07-05-
526	2021 before issuance of registration le Name and address of manufacturer /	
536.		M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLACAM-10 Injection 50ml
	Strength	
	Composition	Each ml contains:
		Meloxicam10mg
	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 sub	omit Rs.7500/- for pre-approval change/correction in
		notification No.F.7-11/2012-B&A/DRAP dated 07-05-
	2021 before issuance of registration le	
537.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
337.		Bypass, Faisalabad.
	Applicant Prond Name Decora Form	
	Brand Name +Dosage Form +	APLACAM-20 Injection 50ml
	Strength	
	Composition	Each ml contains:
	T 1: X1 1 . 0 C	Meloxicam20mg
	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
	<u>I</u>	

		correction in finished product specifications before issuance of registration letter.
		omit Rs.7500/- for pre-approval change/correction in notification No.F.7-11/2012-B&A/DRAP dated 07-05-
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: Meloxicam20mg
	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.
539.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	APLACAM-20 Injection 10ml
	Strength	
	Composition	Each ml contains:
		Meloxicam20mg
	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.
		omit Rs.7500/- for pre-approval change/correction in notification No.F.7-11/2012-B&A/DRAP dated 07-05-tter.

540.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road			
	Applicant	Bypass, Faisalabad.			
	Brand Name +Dosage Form +	APLACAM-5 Injection 50ml			
	Strength	- J			
	Composition	Each ml contains: Meloxicam5mg			
	Composition				
	Tracking Id, date & fee	JB6-R63-5BL1 dated 27-02-2024 Rs 30,000/- dated 23-			
	Trucking ra, date & ree	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			
	Ne too status	Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No.			
		108991)			
	GMP status	New Section			
	Remarks of the Evaluator	Target Species:			
	Remarks of the Evaluator	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				
	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 le				
541.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road			
0.11	Applicant	Bypass, Faisalabad.			
	Brand Name +Dosage Form +	APLACAM-5 Injection 100ml			
	Strength				
	Composition	Each ml contains:			
	r	Meloxicam5mg			
		PLM-45G-AXVG dated 01-03-2024 Rs 30,000/- dated			
	Tracking Id, date & fee	PLM-45G-AXVG dated 01-03-2024 Rs 30,000/- dated			
	Tracking Id, date & fee	•			
	C .	27-02-2024 (Slip No. 164369059207)			
	Pharmacological Group	· ·			
	Pharmacological Group Type of Form	27-02-2024 (Slip No. 164369059207) NSAID Form 5			
	Pharmacological Group Type of Form Finished product Specification	27-02-2024 (Slip No. 164369059207) NSAID Form 5 As per innovator's Specifications			
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	27-02-2024 (Slip No. 164369059207) NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled			
	Pharmacological Group Type of Form Finished product Specification	27-02-2024 (Slip No. 164369059207) NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds			
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	27-02-2024 (Slip No. 164369059207) NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No.			
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	27-02-2024 (Slip No. 164369059207) NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992)			
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	27-02-2024 (Slip No. 164369059207) NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No.			
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	27-02-2024 (Slip No. 164369059207) NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992) New Section Target Species:			
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	27-02-2024 (Slip No. 164369059207) NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992) New Section Target Species: Cattle, buffalo, Sheep, camel, goats, Dogs, cats, horses			
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	27-02-2024 (Slip No. 164369059207) NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992) New Section Target Species: Cattle, buffalo, Sheep, camel, goats, Dogs, cats, horses Shortcomings:			
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	27-02-2024 (Slip No. 164369059207) NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992) New Section Target Species: Cattle, buffalo, Sheep, camel, goats, Dogs, cats, horses			
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	27-02-2024 (Slip No. 164369059207) NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992) New Section 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			
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	27-02-2024 (Slip No. 164369059207) NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992) New Section Target Species: Cattle, buffalo, Sheep, camel, goats, Dogs, cats, horses Shortcomings: Official monograph of the applied formulation is			
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator	NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992) New Section 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.			
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved. Firm shall sulfinished product specifications as per	NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992) New Section 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. bmit Rs.7500/- for pre-approval change/correction in r notification No.F.7-11/2012-B&A/DRAP dated 07-05-			
542.	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved. Firm shall sulfinished product specifications as per 2021 before issuance of registration leads	NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992) New Section 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. bmit Rs.7500/- for pre-approval change/correction in r notification No.F.7-11/2012-B&A/DRAP dated 07-05-etter.			
542.	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved. Firm shall sulfinished product specifications as per 2021 before issuance of registration to Name and address of manufacturer /	NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992) New Section 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. Imit Rs.7500/- for pre-approval change/correction in r notification No.F.7-11/2012-B&A/DRAP dated 07-05-etter. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road			
542.	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved. Firm shall sulfinished product specifications as per 2021 before issuance of registration let Name and address of manufacturer / Applicant	NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992) New Section 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. bmit Rs.7500/- for pre-approval change/correction in r notification No.F.7-11/2012-B&A/DRAP dated 07-05-etter. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.			
542.	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved. Firm shall sulfinished product specifications as per 2021 before issuance of registration to Name and address of manufacturer /	NSAID Form 5 As per innovator's Specifications 100ml; Decontrolled Camrold 5 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 108992) New Section 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. Imit Rs.7500/- for pre-approval change/correction in r notification No.F.7-11/2012-B&A/DRAP dated 07-05-etter. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road			

Composition Each ml contains: Vitamin A100000 IU					
Vitamin A100000 1U					
Vitamin D340000 IU					
Vitamin E40mg					
Tracking Id, date & fee 243-P2P-4U4H dated 27-02-2024 Rs 30,000/- da	ted 23-				
	02-2024 (Slip No. 1205134962)				
	Vitamins				
71	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) New Section				
Remarks of the Evaluator Target Species:					
Cattle, calves, sheep, goats, horses Decision: Approved.					
543. Name and address of manufacturer / M/s Aptly Pharmaceuticals, 5-Km, Sargodh	a Road				
Applicant Bypass, Faisalabad.	u Houu				
Brand Name +Dosage Form + APLA AD3E Injection 50ml					
Strength THE EXTENSE INJection Some					
Composition Each ml contains:					
Vitamin A100000 IU					
Vitamin D340000 IU					
Vitamin E4000 TC Vitamin E40mg					
	atad 26				
02-2024 (Slip No. 24250160)	95S-UA2-3Z5D dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 24250160)				
	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 Pharmac	ceuticals				
(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 / M/s Aptly Pharmaceuticals, 5-Km, Sargodh	a Road				
Applicant Bypass, Faisalabad.					
Brand Name +Dosage Form + APLA AD3E Injection 20ml					
Strength					
Composition Each ml contains:					
Vitamin A100000 IU					
Vitamin D340000 IU					
Vitamin E40mg					
vitatiini Eviiig	dated				
Tracking Id, date & fee 8WN-R1X-47UA dated 01-03-2024 Rs 30,000/-					
Tracking Id, date & fee 8WN-R1X-47UA dated 01-03-2024 Rs 30,000/-					
Tracking Id, date & fee 8WN-R1X-47UA dated 01-03-2024 Rs 30,000/-27-02-2024 (Slip No. 3631729002)					
Tracking Id, date & fee 8WN-R1X-47UA dated 01-03-2024 Rs 30,000/- 27-02-2024 (Slip No. 3631729002) Pharmacological Group Vitamins					
Tracking Id, date & fee 8WN-R1X-47UA dated 01-03-2024 Rs 30,000/-27-02-2024 (Slip No. 3631729002) Pharmacological Group Vitamins Type of Form Form 5					
Tracking Id, date & fee 8WN-R1X-47UA dated 01-03-2024 Rs 30,000/- 27-02-2024 (Slip No. 3631729002) Pharmacological Group Vitamins Type of Form Form 5 Finished product Specification Pack size & Demanded 20ml; Decontrolled	,				
Tracking Id, date & fee 8WN-R1X-47UA dated 01-03-2024 Rs 30,000/- 27-02-2024 (Slip No. 3631729002) Pharmacological Group Vitamins Type of Form Form 5 Finished product Specification Pack size & Demanded As per innovator's Specifications 20ml; Decontrolled	,				
Tracking Id, date & fee 8WN-R1X-47UA dated 01-03-2024 Rs 30,000/- 27-02-2024 (Slip No. 3631729002) Pharmacological Group Vitamins Type of Form Form 5 Finished product Specification Pack size & Demanded Me-too status ADEKA Injection of M/s A & K Pharmaceutical	,				
Tracking Id, date & fee 8WN-R1X-47UA dated 01-03-2024 Rs 30,000/- 27-02-2024 (Slip No. 3631729002) Pharmacological Group Vitamins Type of Form Form 5 Finished product Specification Pack size & Demanded Me-too status ADEKA Injection of M/s A & K Pharmaceutical Faisalabad. (Reg. No.075792)	,				
Tracking Id, date & fee 8WN-R1X-47UA dated 01-03-2024 Rs 30,000/- 27-02-2024 (Slip No. 3631729002) Pharmacological Group Vitamins Type of Form Form 5 Finished product Specification Pack size & Demanded Me-too status ADEKA Injection of M/s A & K Pharmaceutical Faisalabad. (Reg. No.075792) GMP status New Section	,				

7.45	N 1 11 C C /				
545.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road			
	Applicant Prond Name - Deserge Form -	Bypass, Faisalabad. MULTEIN Injection 250ml			
	Brand Name +Dosage Form + Strength	MOLTEIN Injection 250iii			
	Composition	Each 100ml contains:			
	Composition	L-Caritine500mg			
		Pyridoxine HCl15mg			
		Cyanocobalamine3mg			
		DL-Acetylmethionine2gm			
		L-Arginine240mg L-Citruline120mg Glycine150mg			
		Aspartic Acid150mg			
		Fructose5gm			
		Thiotic Acid20mg			
		L-Ornithine120mg			
		L-Lysine50mg			
		Taurine150mg			
		Glutamic Acid150mg			
		Sorbitol8gm			
	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 Vetzpower Injection of M/s Vetz Pharmaceuticals			
	Me-too status	(Private) Limited., Kotri Sindh. (Reg. No. 088074)			
	CMD states	New Section (Private) Limited., Kotri Sindh. (Reg. No. 088074)			
	GMP status Remarks of the Evaluator				
	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 o				
546.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road			
	Applicant	Bypass, Faisalabad.			
	Brand Name +Dosage Form +	MENIXIN-50 Injection 50ml			
	Strength	, and the second			
	Composition	Each ml contains:			
		Flunixin Meglumine50mg			
	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.)			
	CMD	Ltd, Bhimber, AJK (Reg. No. 119708)			
	GMP status	New Section			
	Remarks of the Evaluator	Target Species: Cattle, camels, sheep, goats, horses, dogs			
		Cattle, camels, sneep, goats, norses, dogs Shortcomings:			
		Firm shall submit fee Rs. 30,000/- for revision of label			
		claim in line with reference product and FPP			
L		ciami in the with reference product and FFF			

Decision: Approved. Firm shall submit Rs.30,000/- for pre-approval change/con label claim in line with reference product and finished product specification notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of reletter. Mame and address of manufacturer / Applicant	s as per gistration lha Road
label claim in line with reference product and finished product specification notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of reletter. 547. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	s as per gistration lha Road
Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength MeNIXIN-50 Injection 20ml	
Applicant Brand Name +Dosage Form + Strength Composition Each ml contains: Flunixin Meglumine	
Brand Name +Dosage Form + Strength Composition Each ml contains: Flunixin Meglumine	dated 26-
Strength Each ml contains: Flunixin Meglumine	dated 26-
Flunixin Meglumine	dated 26-
Tracking Id, date & fee EU8-462-72RH dated 29-02-2024 Rs 30,000/- 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 Pharmacet 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 revisic claim in line with reference product specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correct claim in line with reference product and finished product specifications as per in No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter 548. Name and address of manufacturer / Applicant Brand Name +Dosage Form + M/s Aptly Pharmaceuticals, 5-Km, Sargo Bypass, Faisalabad. Brand Name +Dosage Form + MENIXIN-50 Injection 10ml Strength Composition Each ml contains: Flumixin Meglumine	dated 26-
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 Pharmacet 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 revisic claim in line with reference product specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correctic claim in line with reference product and finished product specifications as per n No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter Applicant Bynass, Faisalabad. Brand Name +Dosage Form + Strength MENIXIN-50 Injection 10ml Tracking Id, date & fee BNX-UNR-V23T dated 01-03-2024 Rs 30,000 27-02-2024 (Slip No. 3077206224) Pharmacological Group NSAID Type of Form Form 5 Finished product Specifications	dated 26-
Type of Form Finished product Specification Pack size & Demanded Me-too status Fluxim-5% Injection of M/s Univet Pharmacet Rawalpindi. (Reg. No.109942) GMP status Remarks of the Evaluator Remarks of the Evaluator Target Species: Cattle, camels, sheep, goats, horses, dogs Shortcomings: Firm shall submit fee Rs. 30,000/- for revisicalism in line with reference product specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correcticalism in line with reference product and finished product specifications as per m No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter 548. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each ml contains: Fluxinin Meglumine	
Finished product Specification Pack size & Demanded Pluxim-5% Injection of M/s Univet Pharmacet Rawalpindi. (Reg. No.109942) GMP status Permarks of the Evaluator Target Species: Cattle, camels, sheep, goats, horses, dogs Shortcomings: Firm shall submit fee Rs. 30,000/- for revisicalism in line with reference product specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correcticalism in line with reference product and finished product specifications as per mo.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter M/s Aptly Pharmaceuticals, 5-Km, Sarged Bypass, Faisalabad. Brand Name +Dosage Form + Strength Composition Each ml contains: Flunixin Meglumine	
Pack size & Demanded Me-too status Me-too status Fluxim-5% Injection of M/s Univet Pharmacet Rawalpindi. (Reg. No.109942) GMP status Remarks of the Evaluator Target Species: Cattle, camels, sheep, goats, horses, dogs Shortcomings: Firm shall submit fee Rs. 30,000/- for revisic claim in line with reference product specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correctic claim in line with reference product and finished product specifications as per m No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter 548. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each ml contains: Flunixin Meglumine	
Pack size & Demanded Me-too status Me-too status Fluxim-5% Injection of M/s Univet Pharmacet Rawalpindi. (Reg. No.109942) GMP status Remarks of the Evaluator Target Species: Cattle, camels, sheep, goats, horses, dogs Shortcomings: Firm shall submit fee Rs. 30,000/- for revisic claim in line with reference product specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correctic claim in line with reference product and finished product specifications as per m No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter 548. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each ml contains: Flunixin Meglumine	
Rawalpindi. (Reg. No.109942) GMP status Remarks of the Evaluator Remarks of the Evaluator Target Species: Cattle, camels, sheep, goats, horses, dogs Shortcomings: Firm shall submit fee Rs. 30,000/- for revisic claim in line with reference product specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correctic claim in line with reference product and finished product specifications as per m No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each ml contains: Flunixin Meglumine	
Rawalpindi. (Reg. No.109942) GMP status Remarks of the Evaluator Remarks of the Evaluator Target Species: Cattle, camels, sheep, goats, horses, dogs Shortcomings: Firm shall submit fee Rs. 30,000/- for revisic claim in line with reference product specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correctic claim in line with reference product and finished product specifications as per m No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each ml contains: Flunixin Meglumine	ticals,
Remarks of the Evaluator Target Species: Cattle, camels, sheep, goats, horses, dogs Shortcomings: Firm shall submit fee Rs. 30,000/- for revision claim in line with reference product specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correctic claim in line with reference product and finished product specifications as per m No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter Name and address of manufacturer / Applicant Brand Name +Dosage Form + MENIXIN-50 Injection 10ml Strength Composition Each ml contains: Flunixin Meglumine	
Cattle, camels, sheep, goats, horses, dogs Shortcomings: Firm shall submit fee Rs. 30,000/- for revision claim in line with reference product specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correctic claim in line with reference product and finished product specifications as per m No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter Name and address of manufacturer / Applicant Bypass, Faisalabad. Brand Name +Dosage Form + Menixin-50 Injection 10ml Strength Composition Each ml contains: Flunixin Meglumine	
Shortcomings: Firm shall submit fee Rs. 30,000/- for revision claim in line with reference product specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correctic claim in line with reference product and finished product specifications as per in No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter Name and address of manufacturer / M/s Aptly Pharmaceuticals, 5-Km, Sargo Bypass, Faisalabad. Brand Name +Dosage Form + MENIXIN-50 Injection 10ml Strength Composition Each ml contains: Flunixin Meglumine	
Shortcomings: Firm shall submit fee Rs. 30,000/- for revision claim in line with reference product specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correctic claim in line with reference product and finished product specifications as per m No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter Name and address of manufacturer / M/s Aptly Pharmaceuticals, 5-Km, Sargo Bypass, Faisalabad. Brand Name +Dosage Form + MENIXIN-50 Injection 10ml Strength Composition Each ml contains: Flunixin Meglumine	
claim in line with reference product specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correctic claim in line with reference product and finished product specifications as per no.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter. Name and address of manufacturer / Applicant Bypass, Faisalabad. Brand Name +Dosage Form + MENIXIN-50 Injection 10ml Strength Each ml contains: Flunixin Meglumine	
specifications as prescribed vide S.R.O. 4 dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correctic claim in line with reference product and finished product specifications as per in No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letters. 548. Name and address of manufacturer / M/s Aptly Pharmaceuticals, 5-Km, Sargor Applicant Bypass, Faisalabad. Brand Name +Dosage Form + MENIXIN-50 Injection 10ml Strength Composition Each ml contains: Flunixin Meglumine	n of label
dated 17-04-2023. Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correctic claim in line with reference product and finished product specifications as per in No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter Name and address of manufacturer / Applicant	
Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correctic claim in line with reference product and finished product specifications as per in No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter M/s Aptly Pharmaceuticals, 5-Km, Sargor Bypass, Faisalabad. Brand Name +Dosage Form + MENIXIN-50 Injection 10ml Strength Composition Each ml contains: Flunixin Meglumine	96(I)/2023
claim in line with reference product and finished product specifications as per in No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter 548. Name and address of manufacturer / Applicant Bypass, Faisalabad. Brand Name +Dosage Form + MENIXIN-50 Injection 10ml Strength Composition Each ml contains: Flunixin Meglumine50mg Tracking Id, date & fee BNX-UNR-V23T dated 01-03-2024 Rs 30,000 27-02-2024 (Slip No. 3077206224) Pharmacological Group NSAID Type of Form Form 5 Finished product Specification As per innovator's Specifications	
Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Bypass, Faisalabad. MENIXIN-50 Injection 10ml MENIXIN-50 Injection 10ml Each ml contains: Flunixin Meglumine	otification
Brand Name +Dosage Form + Strength Composition Each ml contains: Flunixin Meglumine50mg Tracking Id, date & fee BNX-UNR-V23T dated 01-03-2024 Rs 30,000 27-02-2024 (Slip No. 3077206224) Pharmacological Group NSAID Type of Form Form 5 Finished product Specification As per innovator's Specifications	lha Road
Strength Composition Each ml contains: Flunixin Meglumine50mg Tracking Id, date & fee BNX-UNR-V23T dated 01-03-2024 Rs 30,000 27-02-2024 (Slip No. 3077206224) Pharmacological Group NSAID Type of Form Form 5 Finished product Specification As per innovator's Specifications	
Composition Each ml contains: Flunixin Meglumine	
Flunixin Meglumine50mg Tracking Id, date & fee BNX-UNR-V23T dated 01-03-2024 Rs 30,000 27-02-2024 (Slip No. 3077206224) Pharmacological Group NSAID Type of Form Form 5 Finished product Specification As per innovator's Specifications	
Tracking Id, date & fee BNX-UNR-V23T dated 01-03-2024 Rs 30,000 27-02-2024 (Slip No. 3077206224) Pharmacological Group NSAID Type of Form Form 5 Finished product Specification As per innovator's Specifications	
27-02-2024 (Slip No. 3077206224) Pharmacological Group NSAID Type of Form Form 5 Finished product Specification As per innovator's Specifications	
Pharmacological Group NSAID Type of Form Form 5 Finished product Specification As per innovator's Specifications	/- dated
Type of Form Form 5 Finished product Specification As per innovator's Specifications	
Finished product Specification As per innovator's Specifications	
Pack size & Demanded 10ml: Deconfrolled	
, , , , , , , , , , , , , , , , , , ,	
Me-too status Floxon Injection of M/s Amazon Pharmaceu Ltd, Bhimber, AJK (Reg. No. 119707)	
GMP status New Section	ical (Pvt.)
Remarks of the Evaluator Target Species:	ical (Pvt.)
Cattle, camels, sheep, goats, horses, dogs	ical (Pvt.)
Shortcomings:	ical (Pvt.)
Firm shall submit fee Rs. 30,000/- for revision in the state of the st	
claim in line with reference product	n of label
specifications as prescribed vide S.R.O. 4	n of label and FPP
dated 17-04-2023.	n of label and FPP
Decision: Approved.Firm shall submit Rs.30,000/- for pre-approval change/correcticlaim in line with reference product and finished product specifications as per n No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter	n of label and FPP 96(I)/2023

F 40	NT 1 11 C C /	M/ A d DI d 1 7 M C II D 1				
549.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road				
	Applicant	Bypass, Faisalabad.				
	Brand Name +Dosage Form +	MENIXIN-83 Injection 50ml				
	Strength					
	Composition	Each ml contains:				
		Flunixin Meglumine83mg				
	Tracking Id, date & fee	839-AXW-XG95 dated 27-02-2024 Rs 30,000/- dated				
	8 1, 1111	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				
		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.				
		t Rs.30,000/- for pre-approval change/correction in label				
		s per notification No.F.7-11/2012-B&A/DRAP dated 07-				
	05-2021 before issuance of registratio					
550.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road				
	Applicant	Bypass, Faisalabad.				
	Brand Name +Dosage Form +	MENIXIN-83 Injection 20ml				
	Strength	J				
	Composition	Each ml contains:				
	Composition	Flunixin Meglumine83mg				
	Tracking Id data & fee	MAR 8VS DI MA dated 20 02 2024 Ps 30 000/ dated				
	Tracking Id, date & fee	MAB-8VS-PLMA dated 29-02-2024 Rs 30,000/- dated				
		26-02-2024 (Slip No. 80219906)				
	Pharmacological Group	26-02-2024 (Slip No. 80219906) NSAID				
	Pharmacological Group Type of Form	26-02-2024 (Slip No. 80219906) NSAID Form 5				
	Pharmacological Group	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications				
	Pharmacological Group Type of Form	26-02-2024 (Slip No. 80219906) NSAID Form 5				
	Pharmacological Group Type of Form Finished product Specification	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications				
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur.				
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365)				
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section				
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section Target Species:				
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section Target Species: Cattle, camels, sheep, goats, horses, dogs				
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section Target Species: Cattle, camels, sheep, goats, horses, dogs Shortcomings:				
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section Target Species: Cattle, camels, sheep, goats, horses, dogs Shortcomings: Firm shall submit fee Rs. 30,000/- for revision of label				
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section 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				
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section 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.				
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved.Firm shall submi	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section 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. t Rs.30,000/- for pre-approval change/correction in label				
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved.Firm shall submiclaim in line with reference product a	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section 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. t Rs.30,000/- for pre-approval change/correction in label s per notification No.F.7-11/2012-B&A/DRAP dated 07-				
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved.Firm shall submiclaim in line with reference product a 05-2021 before issuance of registration	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section 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. t Rs.30,000/- for pre-approval change/correction in label s per notification No.F.7-11/2012-B&A/DRAP dated 07-in letter.				
551.	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved.Firm shall submiclaim in line with reference product a	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section 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. t Rs.30,000/- for pre-approval change/correction in label s per notification No.F.7-11/2012-B&A/DRAP dated 07-				
551.	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved.Firm shall submiclaim in line with reference product a 05-2021 before issuance of registration	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section 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. t Rs.30,000/- for pre-approval change/correction in label s per notification No.F.7-11/2012-B&A/DRAP dated 07-in letter.				
551.	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved.Firm shall submiclaim in line with reference product a 05-2021 before issuance of registration Name and address of manufacturer / Applicant	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section 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. t Rs.30,000/- for pre-approval change/correction in label s per notification No.F.7-11/2012-B&A/DRAP dated 07-n letter. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.				
551.	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved.Firm shall submiclaim in line with reference product a 05-2021 before issuance of registratio Name and address of manufacturer / Applicant Brand Name +Dosage Form +	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section 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. t Rs.30,000/- for pre-approval change/correction in label s per notification No.F.7-11/2012-B&A/DRAP dated 07-n letter. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road				
551.	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved.Firm shall submiclaim in line with reference product a 05-2021 before issuance of registration Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section 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. t Rs.30,000/- for pre-approval change/correction in label s per notification No.F.7-11/2012-B&A/DRAP dated 07-n letter. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 50ml				
551.	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved.Firm shall submiclaim in line with reference product a 05-2021 before issuance of registratio Name and address of manufacturer / Applicant Brand Name +Dosage Form +	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section 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. t Rs.30,000/- for pre-approval change/correction in label s per notification No.F.7-11/2012-B&A/DRAP dated 07-n letter. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 50ml Each ml contains:				
551.	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved.Firm shall submiclaim in line with reference product a 05-2021 before issuance of registration Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section 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. t Rs.30,000/- for pre-approval change/correction in label s per notification No.F.7-11/2012-B&A/DRAP dated 07-n letter. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 50ml Each ml contains: Ketoprofen				
551.	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Approved.Firm shall submiclaim in line with reference product a 05-2021 before issuance of registration Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	26-02-2024 (Slip No. 80219906) NSAID Form 5 USP Specifications 20ml; Decontrolled Fumin 8.3% Injection of M/s Farm Aid Group, Haripur. (Reg. No.117365) New Section 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. t Rs.30,000/- for pre-approval change/correction in label s per notification No.F.7-11/2012-B&A/DRAP dated 07-n letter. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 50ml Each ml contains:				

	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		
		o-committee on Veterinary Drugs regarding therapeutic	
	requirement keeping in view safety,		
552.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road	
	Applicant	Bypass, Faisalabad.	
	Brand Name +Dosage Form +	APLAFENIK Injection 100ml	
	Strength	Each ml contains:	
	Composition	Ketoprofen100mg	
	Tracking Id, date & fee	Z91-16X-2WWA dated 29-02-2024 Rs 30,000/- dated	
	Tracking id, date & fee	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)	
	ivic-too status	Ltd., Lahore (Reg. No. 043141)	
	GMP status	New Section	
	Remarks of the Evaluator	New Section	
	Remarks of the Evaluator		
	Decision: Deferred for review of Sub	o-committee on Veterinary Drugs regarding therapeutic	
	requirement keeping in view safety,	efficacy and quality parameters.	
553.	Name and address of manufacturer /	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road	
553.	Name and address of manufacturer / Applicant	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form +	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form +	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains:	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen100mg BGU-193-6QQ1 dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 667493224) NSAID	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen100mg BGU-193-6QQ1 dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 667493224) NSAID Form 5 As per innovator's Specifications	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for review of Subsections	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
553.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for review of Subrequirement keeping in view safety, Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for review of Subrequirement keeping in view safety, Name and address of manufacturer / Applicant	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for review of Subrequirement keeping in view safety, Name and address of manufacturer / Applicant Brand Name +Dosage Form +	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for review of Subrequirement keeping in view safety, Name and address of manufacturer / Applicant	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for review of Subrequirement keeping in view safety, Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Tracking Id, date & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Me-too status GMP status Remarks of the Evaluator Decision: Deferred for review of Subrequirement keeping in view safety, Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	efficacy and quality parameters. M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. APLAFENIK Injection 20ml Each ml contains: Ketoprofen	

	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.			
	C) (D)	(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 sub	omit 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 le	tter.			
555.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road			
	Applicant	Bypass, Faisalabad.			
	Brand Name +Dosage Form +	IVERCLOTIN Injection 10ml			
	Strength	3			
	Composition	Each ml contains:			
	Composition	Ivermectin10mg			
		Clorsulon100mg			
	Tracking Id, date & fee	576-AW6-UML4 dated 01-03-2024 Rs 30,000/- dated			
	Tracking id, date & rec	27-02-2024 (Slip No. 11312122)			
	Pharmacological Group	Antiparasitic/anthelmintic			
		Form 5			
	Type of Form 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,			
	C) C	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.			
		omit 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 le				
556.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road			
	Applicant	Bypass, Faisalabad.			
	Brand Name +Dosage Form +	IVERCLOTIN Injection 100ml			
	Strength				
	Composition	Each ml contains:			
		Ivermectin10mg			
		Clorsulon100mg			
	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,			
	ivie-too status				
	CMD status	Haripur. (Reg. No. 117259)			
1	GMP status	New Section			

	Remarks of the Evaluator	Shortcomings:		
	Remarks of the Evaluator	Firm shall submit Rs. 7500/- for correction in finished		
		product specifications before issuance of registration		
		1		
	letter. Decisions Approved Firm shall submit Be 7500/, for the approved shange/sourcetion			
	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 le			
557.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road		
	Applicant	Bypass, Faisalabad.		
	Brand Name +Dosage Form +	NIXINIL-34 Injection 100ml		
	Strength			
	Composition	Each ml contains:		
		Nitroxynil340mg		
	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 /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road		
	Applicant	Bypass, Faisalabad.		
	Brand Name +Dosage Form +	NIXINIL-34 Injection 10ml		
	Strength			
	Composition	Each ml contains:		
		Nitroxynil340mg		
	Tracking Id, date & fee	XE9-HDH-U24Y dated 01-03-2024 Rs 30,000/- dated		
	71	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		
	G1 FD	Pharmaceuticals, Islamabad. (Reg. No. 106697)		
	GMP status	New Section		
	Remarks of the Evaluator	Target Species:		
	D	Cattle, sheep, goats		
559.	Decision: Approved. Name and address of manufacturer /	M/a Anthy Dhamma anticala 5 V C II. D. 1		
559.		M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road		
	Applicant Brand Name +Dosage Form +	Bypass, Faisalabad. NIXINIL-20 Injection 50ml		
		NIXINIL-20 Injection 30iii		
	Strength Composition	Each ml contains:		
	Composition	Nitroxynil200mg		
	Tracking Id, date & fee	HH1-T1R-8H15 dated 27-02-2024 Rs 30,000/- dated 23-		
	Tracking id, date & fee	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		
	rack size & Demanded	John, Decontrolled		

	Me-too status	Tronox-200 Injection (100ml) of M/s Nawal
	ivie-too status	Pharmaceuticals, Taxila, Rawalpindi. (Reg. No. 099040)
	GMP status	New Section
	Remarks of the Evaluator	Target Species:
	Remarks of the Evaluator	Cattle, sheep, goats
	Decision: Approved.	Canada, Salada, Sound
560.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	NIXINIL-20 Injection 10ml
	Strength	
	Composition	Each ml contains:
	-	Nitroxynil200mg
	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.	<u>_</u>
561.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	IMIDOCA Injection 50ml
	Strength	
	Composition	Each ml contains:
	T 1' 11 1 0 C	Imidocarb Dipropionate120 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.
		omit Rs.30,000/- for pre-approval change/correction in
		roduct as per notification No.F.7-11/2012-B&A/DRAP
	dated 07-05-2021 before issuance of r	
562.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road
	Applicant	Bypass, Faisalabad.
	Brand Name +Dosage Form +	IMIDOCA 10ml Injection
	Strength	Probable and a service as
	Composition	Each ml contains:
	Totaline II days 0 C	Imidocarb Dipropionate120 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 sub	mit Rs.30,000/- for pre-approval change/correction in			
	label claim in line with reference p	roduct as per notification No.F.7-11/2012-B&A/DRAP			
	dated 07-05-2021 before issuance of r				
563.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road			
	Applicant	Bypass, Faisalabad.			
	Brand Name +Dosage Form +	APYMYRA Injection 50ml			
	Strength				
	Composition	Each ml contains:			
		Mepyramine Maleate50mg			
	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.	T			
564.	Name and address of manufacturer /	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road			
	Applicant	Bypass, Faisalabad.			
	Brand Name +Dosage Form +	APYMYRA Injection 10ml			
	Strength				
	Composition	Each ml contains:			
	T 1: 11 1 0 C	Mepyramine Maleate50mg			
	Tracking Id, date & fee	AYX-YQZ-1GAT dated 01-03-2024 Rs 30,000/- dated			
	N 1 1 1 G	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,			
	G) E	Faisalabad (Reg. No. 069623)			
	GMP status	New Section			
	Remarks of the Evaluator	Target Species:			
		Livestock, sheep, dogs			
		stration 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: Racecadotril10mg	
	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,	

	manufac controls, validatio reference	turers, desc specification, batch and e standard,	ription of manufa ions, analytical alysis and justifica	ties, physical form, acturing process and procedures and its tion of specification, system and stability act.
Module-III Drug Substance:	nomencl physical process a its valida reference	ature, structorm, manuand controls, ation, batch a	eture, general pro ifacturers, descript specifications, and analysis and justific container closure	stance data related to operties, solubilities, ion of manufacturing lytical procedures and ation of specification, system and stability
Stability Studies of Drug Su (Conditions & duration of studies)	Stability substanc The acce ± 5% R	e at both accelerated stabil RH for 6 m	celerated as well as lity data is conducte	of 3 batches of drug s real time conditions. ad at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$ ime stability data is H for 24 months.
Module-III Drug Product:	descripti manufac process drug pro of analy specifica	on, compo ture, manuf validation pr duct, specific ytical proces	sition, pharmace facturing process rotocols, control of cations, analytical p dures, batch anal ence standard or	product including its utical development, and process control, excipients, control of procedures, validation ysis, justification of materials, container
Pharmaceutical Equivaler Comparative Dissolution Pro	ofile product Granules Limited Firm has innovato	against the s for oral s United King s submitted (or's product	innovator's produ uspension manufa- dom CDP results of the	equivalence of their act Hidrasec 10 mg, ctured by Bioproject ir product against the g, Granules for oral
Analytical validation/verification of pro		Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
,	STABILITY STU	JDY DATA		
Manufacturer of API		-		, Ltd Qiangjin Street, an, Shandong, China
API Lot No.	22060IR	.0		
Description of Pack (Container closure system)	Alumini	Aluminium Sachet		
Stability Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
		55NS02	T-055NS03	T-055NS04
Batch No.	T-05	311502		
Batch No. Batch Size		Sachet	500 Sachet	500 Sachet
	500		500 Sachet 02-2023	500 Sachet 02-2023

No. of E	Batches	03
	DOCUMENTS / DATA TO BE PRO	OVIDED ALONG WITH STABILITY STUDY DATA
1.	Reference of previous approval applications with stability study da of the firm (if any)	
2.	* *	Firm has submitted copy of GMP Certificate (No. G/2/173) dated 29-01-2022 issued by Food and Drugs Control of Administration CHINA. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement API with approval from DRAP case of import).	
4.	Data of stability batches will supported by attested respecti documents like chromatograms, Radata sheets, COA, summary dasheets etc.	we Firm has submitted analytical record for product testing.
5.		Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remark	ks of Evaluator:	
	n: Approved.	
•	Manufacturer will place first three proposed shelf life and on accelerate the registration application. Manufacturer will perform process submitted in the registration application.	
•	Manufacturer will place first three proposed shelf life and on accelerate the registration application. Manufacturer will perform process	d studies for six months as per the commitment submitted in validation of first three batches as per the commitment
•	Manufacturer will place first three proposed shelf life and on accelerate the registration application. Manufacturer will perform process submitted in the registration applicate Name, address of Applicant / Marketing Authorization	d studies for six months as per the commitment submitted in a validation of first three batches as per the commitment ion. M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
•	Manufacturer will place first three proposed shelf life and on accelerate the registration application. Manufacturer will perform process submitted in the registration applicate Name, address of Applicant / Marketing Authorization Holder Name, address of Manufacturing	d studies for six months as per the commitment submitted in a validation of first three batches as per the commitment ion. M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post
•	Manufacturer will place first three proposed shelf life and on accelerate the registration application. Manufacturer will perform process submitted in the registration applicate Name, address of Applicant / Marketing Authorization Holder Name, address of Manufacturing site.	d studies for six months as per the commitment submitted in a validation of first three batches as per the commitment ion. M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. Manufacturer Importer
•	Manufacturer will place first three proposed shelf life and on accelerate the registration application. Manufacturer will perform process submitted in the registration applicate Name, address of Applicant / Marketing Authorization Holder Name, address of Manufacturing site. Status of the applicant	d studies for six months as per the commitment submitted in a validation of first three batches as per the commitment ion. M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. Manufacturer Importer Is involved in none of the above (contract giver) Firm has submitted copy of GMP certificate dated 28-12-2021/
•	Manufacturer will place first three proposed shelf life and on accelerate the registration application. Manufacturer will perform process submitted in the registration applicate Name, address of Applicant / Marketing Authorization Holder Name, address of Manufacturing site. Status of the applicant GMP status of the firm Evidence of approval of	d studies for six months as per the commitment submitted in a validation of first three batches as per the commitment ion. M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. Manufacturer Importer Is involved in none of the above (contract giver) Firm has submitted copy of GMP certificate dated 28-12-2021/ based on inspection conducted on 24/11/2021 Firm has submitted copy of letter of grant of section dated 13-01-
•	Manufacturer will place first three proposed shelf life and on accelerate the registration application. Manufacturer will perform process submitted in the registration applicate Name, address of Applicant / Marketing Authorization Holder Name, address of Manufacturing site. Status of the applicant GMP status of the firm Evidence of approval of manufacturing facility	d studies for six months as per the commitment submitted in a validation of first three batches as per the commitment ion. M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. Manufacturer Importer Is involved in none of the above (contract giver) Firm has submitted copy of GMP certificate dated 28-12-2021/based on inspection conducted on 24/11/2021 Firm has submitted copy of letter of grant of section dated 13-01-2022 specifying sachet (General) section. New Drug Product (NDP) Generic Drug Product (GDP)

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	Each sachet contains:
Active Pharmaceutical ingredient (API) per unit	Racecadotril30mg
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. It has summarized information related to nomenclature, struct general properties, solubilities, physical form, manufacture description of manufacturing process and controls, specification analytical procedures and its validation, batch analysis justification of specification, reference standard, contact closure system and stability studies of drug substance and product.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubilities, physicorm, manufacturers, description of manufacturing process controls, specifications, analytical procedures and its validate batch analysis and justification of specification, referestandard, container closure system and stability studies of substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of substance at both accelerated as well as real time conditions. accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 8$ RH for 6 months. The real time stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months.
Module-III Drug Product:	Firm has submitted data of drug product including its descript composition, pharmaceutical development, manufacturing process and process control, process validate protocols, control of excipients, control of drug process pecifications, analytical procedures, validation of analyty procedures, batch analysis, justification of specification reference standard or materials, container closure system 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	method Firm has submitted analytical method validation study reports for drug substance as well as drug product.			
	STAF	BILITY STUDY DATA			
Manufacturer of API		Shandong Boyuan Pharmaceutical Co., Ltd Qiangjin Street, Jibei Economic Development Zone, Jinan, Shandong, China			
API Lot N	0.	22060IRO			
Description (Container	n of Pack closure system)	Aluminium Sac	chet		
Stability S	torage Condition		$C \pm 2^{\circ}C / 65\% \pm 5\%RI$ $0^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%$		
Time Perio	od	Real time: 6 mc			
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	
Manufactu	ring Date	02-2023	02-2023	02-2023	
Date of Ini	tiation	27-01-2023	27-01-2023	27-01-2023	
No. of Bat	ches		03		
D	OCUMENTS / DATA TO BE PRO	OVIDED ALON	G WITH STABILIT	ΓY 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.				
5.		Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.			
6.		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

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		properties, solubilities, physica manufacturing process and procedures and its validation specification, reference stand stability studies of drug substan	controls, specific , batch analysis ar lard, container clo	ations, analytical ad justification of sure system and
nomenclature, structure, general properties, solubit form, manufacturers, description of manufacturing controls, specifications, analytical procedures and batch analysis and justification of specification, refer container closure system and stability studies of drug. Stability Studies of Drug Substance (Conditions & duration of stability data is conducted at 40°C ± 2°C / 75% ±		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.		
		at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / 75% \pm 5% RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / 65%		
		manufacture, process validation f drug product, on of analytical ications, reference		
	Pharmaceutical Equivalence and Comparative Dissolution Profile Firm has submitted pharmaceutical equivalence of their proagainst the innovator's product Catafast sachet 50mg, manuby 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 n		ng, manufactured gainst the	
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.		study reports for
	ST	TABILITY STUDY DATA		
Manufacture	r of API	Henan Dongtai Pharm., Co Ltc County Anyang City Henan Cl		ni Road, Tangyin
API Lot No.		303210413-5		
Description of Pack (Container closure system)		Aluminium Sachet		
Stability Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T 001	T 002	T 003
Batch Size		500 Sachet	500 Sachet	500 Sachet
Manufacturin	ng Date	09-2022	09-2022	09-2022
Date of Initia	tion	26-09-2022	26-09-2022	26-09-2022
No. of Batch	es	03		
DO	CUMENTS / DATA TO BE F	PROVIDED ALONG WITH S	TABILITY STUD	Y DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	manufacturer issued by	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.		Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	for temperature and humidity	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 specifications of the manufacturer are BP and you are referring USP specifications. 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 specifications 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 specifications. 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 M/s Shaigan Pharmaceuticals Pvt Ltd., 14-Km **Authorization Holder** Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. Name, address of Manufacturing site. M/s Shaigan Pharmaceuticals Pvt Ltd., 14-Km Advala Road, Post Office Dahgal, Rawalpindi Pakistan. Status of the applicant ☐ 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 Firm has submitted copy of letter of grant of section dated facility 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 Each 5ml contains: Pharmaceutical ingredient (API) per unit 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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		bmitted analytical n	
	STABILITY	•		as drug product.
Manufacturer of API		Surge Laboratories (Private) Limited Pakistan 10th KM, Faisalabad Road Bikhi, District Sheikhupura – Pakistan.		
API Lo	ot No.	CTM-1-663		
-	ption of Pack iner closure system)	White Plastic Bottle		
Stabilit	ty Storage Condition		$0^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$ $40^{\circ}C \pm 2^{\circ}C / 75\% \pm$	
Time P	Period	Real time: 6 Accelerated:		
Freque	ncy		0, 3, 6 (Months) 0, 3, 6 (Months)	
Batch 1	No.	T-001	T-002	T-003
Batch S	Size	300 bottles	300 bottles	300 bottles
Manuf	acturing Date	08-2022	08-2022	08-2022
Date of	f Initiation	27-08-2022	27-08-2022	27-08-2022
No. of	Batches		03	
DOCUMENTS / DATA TO BE PROVIDEI		ALONG W	ITH STABILITY S	TUDY 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.	(189/2022-D issued by Drucertificate sp	RAP(AD-99778029	213) dated 22/10/2022 ority of Pakistan. The is operating at
3.	Documents for the procurement of API with approval from DRAP (in case of import).	on 20-07-202	22 specifying 18.500	nercial invoice cleared 0Kg of clarithromycin. haigan 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 analytical record for product testing		ord for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		stem along with aud	21 CFR compliance for it trail report for
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	temperature a	mitted record of digi and humidity monito tability chambers.	tal data logger for ring of real time and

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

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.
- 1. 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 specifications, justification is required for mentioning pH limits 3.5-7.0, however USP limits are 4.0-5.4.
- o. Justification for dissolution specifications 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°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 specifications.
- s. Clarification required as Class III solvents are being used in the manufacturing process however their residual limits are not specified in the final specifications.
- 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°C during the manufacturing process form almost 10-12 hours for two times and also at 45-55°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 specifications 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.

: Registration Board deferred the case for su	ubmission of reply to the above cited shortcomings
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: Clarithromycin250mg
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{RH}$	

		Accelerated:	$40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm$	5%RH	
Time Period		Real time: 6 months Accelerated: 6 months			
Frequer	ney		0, 3, 6 (Months) 0, 3, 6 (Months)		
Batch N	No.	T-001	T-002	T-003	
Batch S	ize	300 bottles	300 bottles	300 bottles	
Manufa	cturing Date	08-2022	08-2022	08-2022	
Date of	Initiation	27-08-2022	27-08-2022	27-08-2022	
No. of 1	Batches		03		
	DOCUMENTS / DATA TO BE PROVIDED	ALONG W	ITH STABILITY S	TUDY 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.	,		213) dated 22/10/2022 ority of Pakistan. The s operating at	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	th Firm has submitted copy of commercial invoice clears on 20-07-2022 specifying 18.5000Kg of clarithromyc The invoice is cleared by dawn Shaigan Pharmaceutic Pvt. Ltd.		0Kg of clarithromycin.	
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			

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.
- 1. 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 specifications, justification is required for mentioning pH limits 3.5-7.0, however USP limits are 4.0-5.4.
- o. Justification for dissolution specifications 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°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 specifications.
- s. Clarification required as Class III solvents are being used in the manufacturing process however their residual limits are not specified in the final specifications.
- 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°C during the manufacturing process form almost 10-12 hours for two times and also at 45-55°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 specifications 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

Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceuticals Pvt. Ltd., 14-KM Adyala Road, Pos 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 of inspection conducted on 24/11/2021
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 13-01-202 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, generation

I Lot No. scription of Pack entainer closure system) bility Storage Condition ne Period quency ch No. ch Size nufacturing Date e of Initiation of Batches	211207010 Amber Colored Bottle Real time: 30°C ± 2°C / 65% ± 3 Accelerated: 40°C ± 2°C / 75% Real time: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) T-001 500 bottles 08-2022 11-08-2022	5%RH	T-003 500 bottles 08-2022 11-08-2022	
scription of Pack ontainer closure system) bility Storage Condition ne Period quency ch No. ch Size nufacturing Date	211207010 Amber Colored Bottle Real time: 30°C ± 2°C / 65% ± 3°Accelerated: 40°C ± 2°C / 75% Real time: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) T-001 500 bottles 08-2022	5%RH ± 5%RH T-002 500 bottles 08-2022	500 bottles 08-2022	
scription of Pack ontainer closure system) bility Storage Condition ne Period quency ch No. ch Size	211207010 Amber Colored Bottle Real time: 30°C ± 2°C / 65% ± 2°C / 75% Real time: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) T-001 500 bottles	5%RH ± 5%RH T-002 500 bottles	500 bottles	
scription of Pack ontainer closure system) bility Storage Condition ne Period quency ch No.	211207010 Amber Colored Bottle Real time: 30°C ± 2°C / 65% ± 3 Accelerated: 40°C ± 2°C / 75% Real time: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) T-001	5%RH ± 5%RH T-002		
scription of Pack ontainer closure system) bility Storage Condition ne Period quency	211207010 Amber Colored Bottle Real time: 30°C ± 2°C / 65% ± 3 Accelerated: 40°C ± 2°C / 75% Real time: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	5%RH ± 5%RH	T-003	
scription of Pack ontainer closure system) bility Storage Condition ne Period	211207010 Amber Colored Bottle Real time: 30°C ± 2°C / 65% ± 3 Accelerated: 40°C ± 2°C / 75% Real time: 6 months Accelerated: 6 months Accelerated: 0, 3, 6 (Months)	5%RH		
scription of Pack entainer closure system) bility Storage Condition	211207010 Amber Colored Bottle Real time: 30°C ± 2°C / 65% ± 2°C / 75% Accelerated: 40°C ± 2°C / 75% Real time: 6 months	5%RH		
scription of Pack entainer closure system)	211207010 Amber Colored Bottle Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 3$	5%RH		
scription of Pack	211207010			
I Lot No.	-			
	Theoer Guotong I narmaceuticar			
Manufacturer of API Hebei Guolong Pharmaceutical Co.,Ltd.				
r r	STABILITY STUDY DATA			
	Firm has submitted analytical i	nethod validation study re		
Suspension manufactured by Pfizer Pakistan Limited Firm has submitted CDP results of their product against the innova			Suspension he innovator's	
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system			
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	both accelerated as well as real data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$	time conditions. The accele $C / 75\% \pm 5\%$ RH for 6 mg	erated stability onths. The real	
Module-III Drug Substance:	structure, general properties, so description of manufacturing analytical procedures and its va of specification, reference st	olubilities, physical form, i process and controls, alidation, batch analysis ar andard, container closure	manufacturers, specifications, and justification	
	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.			
	Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Pharmaceutical Equivalence and Comparative Dissolution Profile Analytical method validation/verification of product	manufacturing process and contand its validation, batch anal reference standard, container cle substance and drug product. Module-III Drug Substance: Firm has submitted detailed dru structure, general properties, so description of manufacturing analytical procedures and its validation, reference stability studies of drug substance (Conditions & duration of Stability studies) Stability Studies of Drug Substance (Conditions & duration of Stability studies) Firm has submitted stability studies of drug substance data is conducted at 40°C ± 2°C time stability data is conducted months. Module-III Drug Product: Firm has submitted data of composition, pharmaceutical data process and process control, pexcipients, control of drug prodivalidation of analytical process pecifications, reference standal and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile Analytical method validation/verification of product STABILITY STUDY DATA	manufacturing process and controls, specifications, analytical multiple and its validation, batch analysis and justification of reference standard, container closure system and stability substance and drug product. Firm has submitted detailed drug substance data related to structure, general properties, solubilities, physical form, in description of manufacturing process and controls, analytical procedures and its validation, batch analysis are of specification, reference standard, container closure stability studies of drug substance. Stability Studies of Drug Substance Stability Studies of Drug Substance Stability Studies of Bright has submitted stability study data of 3 batches of drug substance. Firm has submitted stability study data of 3 batches of drug stability studies are alt time conditions. The accelerated as well as real time conditions. The accelerated as well as true and a stability study data of 3 batches of drug substance as well as drug product including it composition, pharmaceutical development, manufacture, process and process control, process validation protoce excipients, control of drug product, specifications, analytic validation of analytical procedures, batch analysis, justice and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile Tirm has submitted pharmaceutical equivalence of their product Zetamax 200mg/5ml Dry Suspension in 3 dissolution product. Firm has submitted analytica	

1.	Reference of previous approval of applications with stability study data of the firm (if any)				
2.	certificate of API manufacturer	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).	specifying 50	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 sub	omitted analytical record for product testing.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has suc	omitted certificate of 21 CFR compliance for the HPLC g with audit trail report for product testing.		
6.		Firm has sub	omitted record of digital data logger for temperature and onitoring of real time and accelerated stability chambers.		
	narks of Evaluator:				
-	ision: Approved.				
Dec	 Manufacturer will place first proposed shelf life and on acc the registration application. Manufacturer will perform submitted in the registration a 	celerated stud process valid application.	ction batches on long term stability studies throughout dies for six months as per the commitment submitted in dation of first three batches as per the commitment M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.		
Dec	 Manufacturer will place first proposed shelf life and on acc the registration application. Manufacturer will perform submitted in the registration a Name, address of Applicant / I 	process validation. Marketing	dies for six months as per the commitment submitted in dation of first three batches as per the commitment M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala		
Dec	 Manufacturer will place first proposed shelf life and on acc the registration application. Manufacturer will perform submitted in the registration a Name, address of Applicant / I Authorization Holder 	process validation. Marketing	dies for six months as per the commitment submitted in dation of first three batches as per the commitment M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd, 14-KM Adyala		
Dec	 Manufacturer will place first proposed shelf life and on acc the registration application. Manufacturer will perform submitted in the registration at Name, address of Applicant / I Authorization Holder Name, address of Manufacturing 	process validation. Marketing	dation of first three batches as per the commitment M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd, 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd, 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. Manufacturer □ Importer		
Dec	 Manufacturer will place first proposed shelf life and on acc the registration application. Manufacturer will perform submitted in the registration a Name, address of Applicant / I Authorization Holder Name, address of Manufacturing Status of the applicant 	process validation. Marketing g site.	dation of first three batches as per the commitment M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd, 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd, 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. Manufacturer Importer Is involved in none of the above (contract giver) Firm has submitted copy of GMP certificate dated 28-12-		
Dec	 Manufacturer will place first proposed shelf life and on acc the registration application. Manufacturer will perform submitted in the registration at Name, address of Applicant / Authorization Holder Name, address of Manufacturing Status of the applicant GMP status of the firm Evidence of approval of manufacturing 	process validation. Marketing g site.	dation of first three batches as per the commitment M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd, 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd, 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. Manufacturer Importer Is involved in none of the above (contract giver) Firm has submitted copy of GMP certificate dated 28-12-2021/ based on inspection conducted on 24/11/2021 Firm has submitted copy of letter of grant of section dated		
Dec	 Manufacturer will place first proposed shelf life and on acc the registration application. Manufacturer will perform submitted in the registration at Name, address of Applicant / I Authorization Holder Name, address of Manufacturing Status of the applicant GMP status of the firm Evidence of approval of manufacturing 	process validation. Marketing g site.	dation of first three batches as per the commitment M/s Shaigan Pharmaceuticals Pvt Ltd., 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd, 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. M/s Shaigan Pharmaceuticals Pvt Ltd, 14-KM Adyala Road, Post Office Dahgal, Rawalpindi Pakistan. Manufacturer Importer Is involved in none of the above (contract giver) Firm has submitted copy of GMP certificate dated 28-12-2021/ based on inspection conducted on 24/11/2021 Firm has submitted copy of letter of grant of section dated 13-01-2022 specifying sachet (General) section. New Drug Product (NDP)		

PKR 30,000/- Dated 03-04-2023

Details of fee submitted

The proposed proprietary name / brand name	ASETIN 200MG SACHET
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Acetylcysteine200mg
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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 sture reports for drug substance as well as drug product.			•
	STABILITY	Y STUDY DATA		
Manu	facturer of API		Hoyo Co, Ltd., No. 1 In Development Zone, Ezhou	
API I	API Lot No. S202205027			
	ription of Pack ainer closure system)	Aluminium Sachet		
Stabil	lity Storage Condition	Real time: 30°C ± 2 Accelerated: 40°C =	2°C / 65% ± 5%RH ± 2°C / 75% ± 5%RH	
Time	Period	Real time: 6 month Accelerated: 6 mon		
Frequ	ency	Accelerated: 0, 3, 6 Real Time: 0, 3, 6 (
Batch	No.	T-055NS02	Batch No.	T-055NS02
Batch	Size	500 Sachet	Batch Size	500 Sachet
Manu	facturing Date	07-2022	Manufacturing Date	07-2022
Date	of Initiation	22-06-2022	Date of Initiation	22-06-2022
No. o	f Batches		03	
	DOCUMENTS / DATA TO BE PROVIDE	ED ALONG WITH	STABILITY STUDY DA	ATA
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.		HB20190479) date Drugs Control Adn	copy of GMP Certificate d 04-03-2019 issued by Folinistration CHINA. The crm is operating at satisfact	ood and ertificate
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared or 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		certificate of 21 CFR con long with audit trail report	•
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		record of digital data logg midity monitoring of real 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.

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	ite. M/s Ferozsons Laboratories Limited P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan ⊠ Manufacturer □ Importer □ Is involved in none of the above (contract giver) 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. of 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. □ New Drug Product (NDP) □ Generic Drug Product (GDP) ccal □ Domestic sale □ Export sale □ Domestic and Export sales Dy. No 24.05.2023 PKR 30,000/- Slip# 9709041254, Dated 16-03-2023 et / TERF CREAM 1% of Each gm contains: Terbinafine hydrochloride10mg PI) Antifungal for topical use White homogenous cream uct JP Specifications 5g, 10g, 15g, 30g, 50g As per SRO ory Lamisil Cream 1% (Approved BY FDA) Terbimax Cream 1% (M/s Maxitech Pharma (Pvt) Ltd.) API Zhejiang East-Asia Pharmaceutical Co., Ltd Address: Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.317100 rall Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template.			
	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				
	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)	Amangarh, Nowshera, Khyber Pakhtunkhwa-Pakistan M/s Ferozsons Laboratories Limited P.O. Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan Manufacturer Importer Is involved in none of the above (contract giver) 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. 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. New Drug Product (NDP) Generic Drug Product (GDP) Domestic sale Export sale Domestic and Export sales Dy. No 24.05.2023 PKR 30,000/- Slip# 9709041254, Dated 16-03-2023 TERF CREAM 1% Each gm contains: Terbinafine hydrochloride10mg Antifungal for topical use White homogenous cream JP Specifications 5g, 10g, 15g, 30g, 50g As per SRO Lamisil Cream 1% (Approved BY FDA) Terbimax Cream 1% (M/s Maxitech Pharma (Pvt) Ltd.) Zhejiang East-Asia Pharmaceutical Co., Ltd Address: Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.317100 Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted QOS as per WHO QOS-PD template. Firm has perifications, analytical procedures and its			
	Name and address of API manufacturer.	Coastal Industrial City, Pubagang town, Sanmen county,			
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and			
	Minutes of 335th meeting of Registration	on Board (25th April 2024) 1052			

	Module-III Drug Substance: Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Module-III Drug Product:		reference standard, container closure system and stability studies of drug substance and drug product. 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.		
Mod					
(Con			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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 48 months. Batches:		
Mod			descrip manufa process drug validat justific	(DC-013-1707001, DC-013-1707002, DC-013-1707003) Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
			Firm has submitted pharmaceutical equivalence of their product against the Innovator product Lamisil Cream 1% manufactured by M/s GSK.		
	ytical ation/verification	method on of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
STABILITY STU	JDY DATA				
Manufacturer of A	ΔPI		M/s Zhejiang East-Asia Pharmaceutical Co., Ltd Industrial City, Pubagang town, Sanmen county, Zhejiang,		
API Lot No.		DC-013-2106003			
Description of Pac (Container closure		Collapsible Alu-T	Гube packed in a unit carton		
Stability Storage (Condition		$C \pm 2^{\circ}C / 75\% \pm 5\% RH$ $\pm 2^{\circ}C / 65\% \pm 5\% RH$		
		Real time: 6 mont Accelerated: 6 mo			
Frequency Accelerated: 0, 3, Real Time: 0, 3, 6					
Batch No.		174NS04		174NS05	174NS06
Batch Size		3000 grams		3000 grams	3000 grams
Manufacturing Da	te	03-2022		03-2022	03-2022
Date of Initiation studies	n of stability	20-04-2022		20-04-2022	20-04-2022
No. of Batches		03			

DOCUMEN	NTS / DATA TO BE PROVIDED ALON	G WITH STABILITY STUDY DATA
1.	1 11	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.		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.		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.		Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	temperature and humidity monitoring of	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.

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 GMP status of the firm		☑ Manufacturer☐ Importer☐ Is involved in none of the above (contract giver)
		GMP certificate valid up to: 27-10-2025
	Evidence of approval of manufacturing facility	Tablet (General) Section, Approval by Central Licensing Board in its 222 nd meeting held on 04 th 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
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 36 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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		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 validation/verification				nalytical method v ll as drug product.	validation study reports for	
1	STA	BILITY STU	DY DA	TA		
Manufacturer of API				ceutical Factory ing District, Chang	gzhou, Jiangsu, China.	
API Lot No.	ZSAP210	0401				
Description of Pack (Container closure system)	along wit	h leaflet.			n Bleach Card unit carton	
Stability Storage Condition		e: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / \text{ted}$: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$				
Time Period		e: 06 months ted: 06 months	S			
Frequency			ed: 0, 3, 6 (Months) e: 0, 3, 6, 9, 12 (Months)			
Batch No.	Tı	rial-03	al-03 Trial-04		Trial-05	
Batch Size	1200) Tablets	ets 1200 Tablets		1200 Tablets	
Manufacturing Date	07	'-2021	07-2021		07-2021	
Date of Initiation	30-0	07-2021	3	0-07-2021	30-07-2021	
No. of Batches		03				
DOCUMENTS / DATA					Y STUDY DATA	
1. Reference of previous approximately study data of the firm (if		lications with	stability	Not required.		
2. Approval of API/ I manufacturer issued by country of origin.						
3. Documents for the procu DRAP (in case of import		PI with approv	val from	Form 6 issuance Quantity: 0.1 kg License No: 0069		
respective documents like	Data of stability batches will be s respective documents like chromatogr COA, summary data sheets etc.				tted analytical record for	
_	Compliance Record of HPLC softwar reports on product testing		re 21CFR & audit trail Firm has submitted compliance for the I audit trail report for		ne HPLC system along with	
6. Record of Digital data logger for tem monitoring of stability chambers (real		•	•	logger for ten	tted record of digital data imperature and humidity real time and accelerated its.	
Remarks of Evaluator:						
Decision: Approved with Innov	ator's specif	ications.				

- 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.

74. 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	
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 222 nd meeting held on 04 th 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 (Qua Summary)	lity Overall	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 S	ubstance)	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 (D	rug Substance)	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 12 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 06 months Aspirin Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 48 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 06 months		
Module-III (Drug F	roduct):	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 eccomparative dissolu	•	Name: Cabpirin 100/10 Tablet Manufacturer: M/s Otsuka Testing parameters: Innovator Specifications Batch # 521559		
Analytical validation/verification		Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.		
	STA	BILITY 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: expi	red in year	2022		
	ADIA	T.	Vonoprazan fu	marate	Aspirin		Aspirin
	API Lot N	NO.	Not provide	ed		No	t provided
	iption of Pacainer closure		30 in ALU-ALU Blis	ter packed	in unit carton	l	
Stabili	ity Storage (Condition	Real time: 30°C ± 2°C Accelerated: 40°C ± 2				
Time I	Period		Real time: 06 months Accelerated: 06 mont				
Freque	ency		Accelerated: 0, 3, 6 (1) Real Time: 0, 3, 6, 9,		24 (Months)		
	Batch N	0.	T-01	Т	-02		T-03
	Batch Si	ze	1200 tablets	1200	tablets		1200 tablets
M	Ianufacturin	g Date	09-2021	09-	2021		09-2021
	Date of Initi	ation	21-09-2021	21-0	9-2021		21-09-2021
	No. of Bate	ches			03		
			Admini	strative P	ortion		
1.	Reference firm (if ar	•	s approval of applications with stability study data of the Not applicable				Not applicable
2.		Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Provided					Provided
3.	Documen import).	ts for the pr	ocurement of API with	approval i	From DRAP (i	in case of	Quantity: 100 kg Invoice # 2122/SL/032 Dated: 05-08-2021
4.			hes will be supported Raw data sheets, COA				Submitted.
5.	Complian testing	ce Record o	of HPLC software 21CF	FR & audit	trail reports or	n product	Submitted
6.		•	ta logger for temperated time and accelerated		umidity moni	toring of	Submitted.
	rks of the I	Evaluator:					
Sec	etion	~1	Observations	g = -			of the firm
1.0	6.5	suppliers fo	submit GMP Certificate of API Submitted for Vonoprazan and Aspirin buld be in force till date.		omitted		
 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? Please submit evidence that innovator brand As one salt is enteric coated and of immediate release so we chose drug of method. The same formulation has been a approved by DRB. Firm has submitted PMDA JAPAN approximation of two incompatible APIs?			we chose drug coating mulation has been already				
	•]	Please subm			Firm has sub	omitted PN	MDA JAPAN approva

		apan, is a vonoprazan coated tablet and not 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.	
	V sı sı	Please clarify whether in process test for Vonoprazan containing drug coating uspension has been performed? If yes, then ubmit validation data as well as analytical esting parameters with reference of testing.	Report submitted	
	eı at	Please submit data regarding weight gain of interic coated tablet of Aspirin before and fter spraying the drug coating suspension ontaining Vonoprazan.	Master formulation along with weight gains at each step Submitted	
	co su in	Please submit documented evidence that the oating machine used for drug coating uspension contains Human machine nterface (HMI) to control the opening and losing of the exhaust during coating time.	g pan e d	
3.2.P.5	di co	Please submit detailed procedure regarding isintegration time requirement for drug oating of vonoprazan and then isintegrating time of enteric coated aspirin.	Submitted	
	• P	lease submit detailed dissolution rocedure 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 247 th meeting of Central Licensing Board held on 29 th 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
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, Hyderaba Telangana, India. GMP validity: compliant
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Fir has summarized information related to nomenclature, structure general properties, solubility, physical form, manufacture description of manufacturing process and controls, specification analytical procedures and its validation, batch analysis a justification 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 nomenclature, structure, general properties, solubility, physic form, manufacturers, description of manufacturing process a controls, specifications, analytical procedures and its validation batch analysis and justification of specification, referent standard, container closure system and stability studies of dr substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 60months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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 validating protocols, control of excipients, control of drug produst specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specification reference standard or materials, container closure system a stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Brand Name: Ondanz Injection 4mg Manufacturer: M/s Welwink Testing Parameters: USP Specifications
	Firm has submitted analytical method validation study reports t

		STABILITY STU	DY DA	TA		
Manufa	Manufacturer of API Name: M/s Changzhou Pharmaceutical Factory Address: Laodong E Rd, Tianning District, Changzhou, Jiangsu,					
API Lot No.		Not provided	1			
Descri	ption of Pack	Glass Ampoules				
	iner closure system)	Glass Ampoures				
Stabilit	ty Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / \text{Accelerated}$: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / \text{Accelerated}$				
Time P	Period	Real time: 06 months Accelerated: 06 months	S			
Freque	ncy	Accelerated: 0, 3, 6 (M Real Time: 0, 3, 6, 9, 12		ns)		
	Batch No.	A001		A002	A003	
	Batch Size	1000 Ampoules	100	00 Ampoules	1000 Ampoules	
	Manufacturing Date	10-2020		10-2020	10-2020	
	Date of Initiation	01-10-2020	0	1-10-2020	01-10-2020	
	No. of Batches			03		
	DOCUMENTS / DATA	ГО BE PROVIDED AL	ONG W	TTH STABILITY	STUDY DATA	
1.	Reference of previous appr study data of the firm (if an		stability	Not required.		
2.	A A	al of API/ DML/GMP certificate of API Submitted sturer issued by concerned regulatory authority of of origin.				
3.	Documents for the procure DRAP (in case of import).	ement of API with approv	al from	Submitted		
4.		Data of stability batches will be supported by attested firm has submitted analytical espective documents like chromatograms, Raw data sheets, product testing.			d analytical record for	
5.	Compliance Record of HPI reports on product testing	LC software 21CFR & au	ıdit trail		HPLC system along with	
6.	Record of Digital data logg		•		d record of digital data	
	monitoring of stability char	mbers (real time and acce	elerated)		erature and humidity I time and accelerated	
	ks of Evaluator:					
Section 1.6.5		Observations MP certificate of API man	urfootus==	ricened by Daculate	Reply of the firm	
1.0.5		y of Origin and should be		• 0	Submitted	
S.2.P.2 Please justify that Pharmaceutical equivalence studies have been perform with a local brand instead of innovator brand /brand leader?		ed As per WHO guidelines.				
3.2.P.	claimed.	e limits of specification	ns subm	itted vs specificati	on Correction done	
3.2.P.		s of this section.		Submitted		
3.2.P.	Please submit DRAF	P clearance for the API in	nport.		Submitted	
	of stability batches.	of API used in product do				
		ation sheets for analysis a elerated and long term stu				

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.

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 180 th meeting held on 03 rd & 4 th 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
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 validit	y : 31-12-2022	
	Module-II (Quality Summary)	Overall	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 Substa	nce):	nomenclature form, manuf controls, spe batch analy	e, structure, general prop facturers, description of n ecifications, analytical pro- sis and justification of	substance data related to erties, solubility, physical nanufacturing process and cedures and its validation, specification, reference d stability studies of drug
	Stability Studies of Drug (Conditions & duration of studies)		Climatic con Real time sta	stability data for 06 month ditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$ bility data for 48 months ditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\%$	± 5% RH.
	Module-III (Drug Product): Pharmaceutical Equivalence and Comparative Dissolution Profile		composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. ce and Brand Name: Lipiget 20 mg Tablet		
	Analytical validation/verification of	product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
		STA	BILITY STU	JDY DATA	
Manufact	turer of API	Address:			r Dera Bassi, Distt. S.A.S
	API Lot No.	L421010	026		
	on of Pack er closure system)		LU Blisters		
5 0		e: 30°C ± 2°C / 65% ± 5%RH ted: 40°C ± 2°C / 75% ± 5%RH			
		e: 06 months ted: 06 months			
Frequenc	•	Real Tim	ted: 0, 3, 6 (Mate: 0, 3, 6, 9, 1	2 (Months)	
Batch No.					
	Batch No.	Т	T-019	T-020	T-021

			1					
	Manufacturing Date	11-2021		11-2021	11-2021			
Date of Initiation 01-01-2022		01	1-01-2022	01-01-2022				
	No. of Batches			03				
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA								
1.	Reference of previous approstudy data of the firm (if any		val of applications with stability Not required.					
2.	Approval of API/ DML/GMP certificate of API Submitted manufacturer issued by concerned regulatory authority of country of origin.							
3.	Documents for the procurer DRAP (in case of import).	ment of API with approv	val from	Submitted				
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets COA, summary data sheets etc.				tted analytical record for			
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing			compliance for th	ted certificate of 21 CFR te HPLC system along with for product testing.			
6.	Record of Digital data logg monitoring of stability chan	•	elerated)	logger for ter	tted record of digital data inperature and humidity real time and accelerated rs.			
Remar	ks of Evaluator:							

Section	Observations	Reply of the firm			
1.3.4	• For the manufacturing facility of Tablet (General) Section, please submit the	Submitted			
	evidence of section approval in the meeting of Central Licensing Board.				
	Please submit fresh / valid GMP certificate issued by DRAP OR inspection <i>Not yet submitted</i>				
	report conducted within last three years.				
1.6.5	• Please submit the GMP certificate of API manufacturer issued by	Expired on			
	Regulatory Authority of Country of Origin and should be inforce till date.	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 241 st meeting held on 15 th 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: Rivaroxaban10mg
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 12 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH

			manufacturir	ng proce	ss and process co	ontrol, process validation
	Pharmaceutical Equivalence and Comparative Dissolution Profile		protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.			
			Manufactur	Brand Name: Rivaxo 10 mg Tablet Manufacturer: M/s Getz Pharma Testing Parameters: Manufacturer Parameters Comparative Dissolution Profile		
				wing sin	milarity between the	solution profile in three he manufacturer's product
	Analytical validation/verification of	method product			nalytical method v ll as drug product.	ralidation study reports for
		STA	BILITY STU	DY DA	TA	
Manufa	acturer of API				armaceutical Co. l at Zone, Huangyan	Ltd. , Taizhou City, China.
	API Lot No.					
	otion of Pack iner closure system)	ALU-AL	U Blisters			
Stabilit	y Storage Condition		e: $30^{\circ}C \pm 2^{\circ}C$ / ted: $40^{\circ}C \pm 2^{\circ}C$			
Time P	Period		ne: 06 months rated: 06 months			
Freque	ncy		ated: 0, 3, 6 (Months) me: 0, 3, 6, 9, 12 (Months)			
	Batch No.	Л	Γ-021		T-022	T-023
	Batch Size	4000) Tablets	40	000 Tablets	4000 Tablets
	Manufacturing Date	03	3-2021		03-2021	03-2021
	Date of Initiation	03	3-2021		03-2021	03-2021
	No. of Batches				03	
	DOCUMENTS / DATA	ГО BE PR	OVIDED AL	ONG W	TTH STABILITY	Y STUDY DATA
1.	Reference of previous appr study data of the firm (if ar		lications with	stability	Not required.	
2.	Approval of API/ DM manufacturer issued by cocountry of origin.			Submitted		
3.	Documents for the procurement of API with approval fro DRAP (in case of import).			val from	Not provided	
4.	Data of stability batches respective documents like COA, summary data sheets			firm has submitted analytical record for product testing.		
5.	Compliance Record of HP reports on product testing	re 21CFR & au	udit trail	Firm has submitted certificate of 21 CFI compliance for the HPLC system along wit audit trail report for product testing.		
6.	Record of Digital data logger for temperature and hu monitoring of stability chambers (real time and accele					ted record of digital data nperature and humidity

		monitoring of real time and accelerated stability chambers.		
Remarks of	Evaluator:			
Section	Observations	S		
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 the stringent than the specification of this formulation a 			
1.6.5	• Please submit the GMP certificate of API manufa Country of Origin and should be inforce till date.	acturer issued by Regulatory Authority of		
3.2.P.2	Please justify that why Lactose monohydrate & Se formulation while the same ingredients in innovator			
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 i Please submit COA of API LOT # used in manufact Please submit reference of analytical method of diss Please submit complete set of chromatograms for ea sheets. Calculation sheets should have essential paraformula etc. 	curing of stability batches. colution. ch interval of testing along with calculation		

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

| Name address of Applicant / M/s Davis Pharmaceutical Laboratories (DML # 000432)

8.	Name, address of Applicant / Marketing Authorization Holder	Islamabad.		
	Name, address of Manufacturing site.			
	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 241 st meeting held on 15 th 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: Rivaroxaban15 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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 12 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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 validation/verification of			alytical method v l as drug product.	validation study reports for	
	1	STABILITY STU	DY DAT	ΓΑ		
Manu	facturer of API	Name: M/s Zhejiang Ti Address: Jiangkou Dev				
	API Lot No.					
	iption of Pack ainer closure system)	ALU-ALU Blisters				
Stabil	ity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / \text{Accelerated}$: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$				
Time	Period	Real time: 06 months Accelerated: 06 months	S			
Frequ	ency	Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6, 9, 12		s)		
	Batch No.	T-024		T-025	T-026	
	Batch Size	4000 Tablets	40	00 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 AL	ONG W	ITH STABILIT	Y STUDY DATA	
1.		proval of applications with				
2.						
3.	Documents for the procus DRAP (in case of import)	ocuments for the procurement of API with approval from <i>Not provided</i>				
4.	respective documents like	Data of stability batches will be supported by attested firm has submitted analytical record for 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 Firm has submitted certificate of 21 CF compliance for the HPLC system along wi 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.					
	rks of Evaluator:					
Secti			ervations			
1.5.6	available in BP F	harmacopeia?	why Manufacturer Specification should be accepted when monograph is armacopeia? dence as per ICH guidelines that Manufacturer specifications are more			
		e specification of this formu			•	
1.6.5		e GMP certificate of API		cturer issued by	Regulatory Authority of	
3.2.F		n and should be inforce till at why Lactose monohydr		adium Lauryl cul	fate are not part of your	
	formulation whil	e the same ingredients in ir	novator	formulation conti	ributes in CQAs?	
3.2.F	2.2.2 • Please justify tha	t why testing parameters of	t BP spec	cifications have n	ot 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.

sion: Registration Board deferred the case for submission of reply to the above cited shortcomings.				
	nddress of Applicant / ing Authorization Holder	M/s Davis Pharmaceutical Laboratories (DML # 000432) Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad.		
Name, site.	address of Manufacturing	M/s Davis Pharmaceutical Laboratories (DML # 000432) Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad.		
Status of	f the applicant	☑ Manufacturer☐ Importer☐ Is involved in none of the above (contract giver)		
GMP sta	atus of the firm	GMP certificate valid up to: 01-02-2024		
Evidenc manufac	e of approval of cturing facility	Central Licensing Board in its 241 st meeting held on 15 th May 2015 approved the renewal of DML of the firm including Tablet (General) Section.		
Status of	f application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)		
Intended	l use of pharmaceutical	 □ Domestic sale □ Export sale ⊠ Domestic and Export sales 		
Dy. No.	and date of submission	Dy. No 23673 dated 22-08-2022		
Details of	of fee submitted	PKR 30,000/-: Dated 31-05-2022 Slip # 928723210		
The prop brand na	posed proprietary name / nme	Rivo 20 mg Tablet		
	/ concentration of drug of Pharmaceutical ingredient er unit	Each Film Coated Tablet contains: Rivaroxaban20 mg		
Pharmac (API)	co-therapeutic Group of	Antithrombotic agents ATC code: B01AF01		
Pharmac drug	ceutical form of applied	Film coated tablets		
Reference	ce to Finished product	Manufacturer Specifications		
Propose	d Pack size	4 x 7s		
Propose	d 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 manufacturer.	of API	Name: M/s Zhejiang Tianyu Pharmaceutical Co. Ltd. Address: Jiangkou Development Zone, Huangyan, Taizhou City, China. GMP validity: 14-03-2023		
Module-II (Quality Summary)	Overall	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 Substar	ace):	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 S (Conditions & duration of studies)		Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 12 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH		
Module-III (Drug Product	i):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
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.		
		Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
	STA	BILITY STUDY DATA		
Manufacturer of API		/s Zhejiang Tianyu Pharmaceutical Co. Ltd. Jiangkou Development Zone, Huangyan, Taizhou City, China.		
API Lot No.				
Description of Pack (Container closure system)	ALU-AL	U Blisters		
Stability Storage Condition		e: 30°C ± 2°C / 65% ± 5%RH ted: 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 (Month				
	Batch No.	T-027		T-028	T-029		
	Batch Size	4000 Tabl	ets 40	000 Tablets	4000 Tablets		
	Manufacturing Date	9 05-2021	I	05-2021	05-2021		
	Date of Initiation	05-2021	L	05-2021	05-2021		
	No. of Batches		1	03			
	DOCUMENTS / I	DATA TO BE PROVII	DED ALONG W	TTH STABILITY	Y STUDY DATA		
1.	Reference of previous study data of the fin	ous approval of application (if any)	ons with stability	Not required.			
2.	* *	PI/ DML/GMP certif d by concerned regulat					
3.	Documents for the DRAP (in case of i	procurement of API witmport).	h approval from	Not provided			
4.		nts like chromatograms,			ted analytical record for		
5.		ompliance Record of HPLC software 21CFR & audit trail 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.						
	ks of Evaluator:						
Section 1.5.6		ify that why Manufact	Observation		oted when monograph is		
1.5.0		n BP Pharmacopeia?	arer specification	n snound be accep	ned when monograph is		
					specifications are more		
1.6.5		nan the specification of t			rmacopeia. Regulatory Authority of		
1.0.5		Origin and should be in		acturer issued by	Regulatory Authority of		
3.2.P.:	Please just formulatio		onohydrate & S		fate are not part of your ibutes in CQAs?		
3.2.P.:	J	ify that why testing para bmit evidence as per I			ot been adopted? specifications are more		
stringent than the specification of this formulation available in BP Pha				ailable in BP Phar			
reference of the method and limits for dissolution test.				. 1 1 1 1 1			
• Please justify that why Manufacturer Specification should be accepted whe available in BP Pharmacopeia?				oted when monograph is			
	• Please submit evidence as per ICH guidelines that Manufacturer specifications are stringent than the specification of this formulation available in BP Pharmacopeia.						
3.2.P.					- P - · · ·		
		mit COA of API LOT #		-	patches.		
		mit reference of analytic			ng alang with sall-t		
	 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. 						

ision: Registration Board deferred the	case for submission of reply to the above cited shortcomings.
0. 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
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	y physical form manufacturers	
			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 Subst	ance):	nomenclature, structure, gene form, manufacturers, descrip controls, specifications, analy batch analysis and justific	d drug substance data related to eral properties, solubility, physical tion of manufacturing process and rtical procedures and its validation, ation of specification, reference system and stability studies of drug	
	Stability Studies of Dru (Conditions & duration studies)		Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 60 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH		
	Pharmaceutical Equivalence and Comparative Dissolution Profile		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
			Brand Name: Cyanocobalamin Injection Manufacturer: M/s Ameer Pharma Testing Parameters: USP specifications		
Analytical method validation/verification of product		Firm has submitted analytical drug substance as well as drug	method validation study reports for g product.		
		STA	BILITY STUDY DATA		
		l/s YUXING Biotechnology (G XiCheng District, Ningjin Cou			
API Lot No. C210720I		D			
Description of Pack (Container closure system)		ass Ampoules			
, ,		e: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ ted: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
		e: 06 months ted: 06 months			
		ted: 0, 3, 6 (Months) e: 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 PR	OVIDED ALONG WITH ST	ABILITY STUDY DATA	
	Reference of previous apputed tudy data of the firm (if a	• •	lications with stability Not req	uired.	
	·				

	Approval of API/ DML/GMP nanufacturer issued by concerned recountry of origin.		Submi	Submitted		
	Documents for the procurement of A DRAP (in case of import).	PI with approval from	Quantity: 5kg Dated: 27-08-2021			
1	Data of stability batches will be sepective documents like chromatogrammary data sheets etc.			firm has submitted analytical record for product testing.		
	Compliance Record of HPLC software ports on product testing	re 21CFR & audit trail	UV sp	ectroscopy		
			logger monite	has submitted record of digital data for temperature and humidity oring of real time and accelerated ty chambers.		
Remark	s of Evaluator:					
Section	Observa	itions		Reply of the firm		
	 Please submit valid / fresh C issued by DRAP OR inspect last three years for confirmation of the manufacturing facility. 	tion report conducted von of GMP compliance	within	Submitted		
1.3.4 • For the manufacturing facility. & ampoules – General Section Section approval in the med Board.		y of Liquid Injectable n), please submit evide	nce of	Firm submitted the renewal of DML mentioning the section.		
Please submit evidence of app in reference regulatory author adopted by the Registration B				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.		
Please submit the GMP certi issued by Regulatory Authori should be inforce till date.		ity of Country of Origin and		Submitted		
			te documents for API import. Submitted			
Please submit details of three manufacturing date, batch size API Lot#.		ee stability batches such as				
Decision	: Deferred for the evidence of RRA	1				
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. ☑ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)				
	Status of the applicant					
	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 283 rd meeting held on 28 th October 2021 approved the grant of additional section Oral Liquid (General) Section.				
	Status of application	☐ New Drug Product (NDP)				
	1					

		⊠ 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 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 ₂ O equivalent to Ondansetron4 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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 60 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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 Comparative Dissolution		Manufacture	er: M/s 1			
	Analytical validation/verification of					alidation study reports for	
			drug substance as well as drug product. BILITY STUDY DATA				
Manufa	octurer of API	Address:	I/s Anugraha Chemicals Research & Development No. D-47 to D-50, C-62 & C-63, KSSIDC Industrial Estate, llapur, Banglore, Karnataka, India.				
	API Lot No.	AOND-2	2005				
	tion of Pack ner closure system)	Amber co	plored 60ml glass bottles packed in unit carton.				
Stability	y Storage Condition		e: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ ted: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$				
Time Pe	eriod		e: 06 months ted: 06 months				
Frequer	ncy		ted: 0, 3, 6 (Mo ie: 0, 3, 6, 9, 12		ns)		
	Batch No.				T-02	T-03	
Batch Size 100			bottles	1	00 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 T				1	STUDY DATA	
	Reference of previous approstudy data of the firm (if an		lications with s	stability	Not required.		
	11	val of API/ DML/GMP certificate of API Submitted facturer issued by concerned regulatory authority of crigin.					
	Documents for the procurement of API with a DRAP (in case of import).			al from	Quanity:5kg Dated: 11-09-202	1	
	Data of stability batches will be supported by respective documents like chromatograms, Raw da COA, summary data sheets etc.				· · · · · · · · · · · · · · · · · · ·		
I II	Compliance Record of HPI reports on product testing	e 21CFR & au	dit trail	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 temp monitoring of stability chambers (real t							
Remark Section	ks of Evaluator:	Ωh	servations			Reply of the firm	
1.6.5	• Please submit the 0			manuf	acturer issued by		
	Regulatory Authority of Country of Origin and should be inforce till date. Submitted						

such as weight in mg/gm of sample & standards, dilutions, formula of	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 	Submitted
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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.

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			
GMP status of the firm			
Evidence of approval of manufacturing facility			
Status of application			
Intended use of pharmaceutical product			
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 ₂ O equivalent to Ondansetron4 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		

I.						
	Name and address manufacturer.	of API	Name: M/s Cipla – Kurkumbh Cipla Limited. Address: No. D-22, MIDC Industrial Area, Kurkumbh Village, Taluka-Daund, District-Pune (Maharashtra), India. GMP validity: <i>not provided</i>			
	Module-II (Quality Summary)	Overall	has summari general pro- description of analytical pro- justification	ized information related to perties, solubility, physic of manufacturing process as rocedures and its valida	QOS-PD template. Firm o nomenclature, structure, cal form, manufacturers, nd controls, specifications, tion, batch analysis and standard, container closure estance and drug product.	
	Module-III (Drug Substar	nce):	nomenclature form, manuf controls, spe batch analy	e, structure, general proper facturers, description of necifications, analytical pro- sis and justification of	substance data related to erties, solubility, physical nanufacturing process and cedures and its validation, specification, reference d stability studies of drug	
	Stability Studies of Drug S (Conditions & duration of studies)		Climatic con Real time sta	stability data for 06 month ditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$ ability data for 60 months ditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\%$	± 5% RH.	
	Module-III (Drug Product):			ng pharmaceutical deving process and process control of excipients, constantly, analytical procedures, batch analysis, justific	et including its description, elopment, manufacture, ontrol, process validation ontrol of drug product, validation of analytical eation of specifications, ainer closure system and	
	Pharmaceutical Equivale Comparative Dissolution					
validation/verification of product			Firm has submitted analytical method validation study reports for drug substance as well as drug product.			
STABILITY STUDY DATA						
Address:		I/s Anugraha Chemicals Research & Development No. D-47 to D-50, C-62 & C-63, KSSIDC Industrial Estate, llapur, Banglore, Karnataka, India.				
API Lot No. 01701012		2106001				
Description of Pack (Container closure system) Amber co		colored 60ml glass bottles packed in unit carton.				
, ,		he: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ htted: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$				
		e: 06 months ted: 06 months				
			ted: 0, 3, 6 (Months) e: 0, 3, 6, 9, 12 (Months)			
	Batch No.	r	Γ-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			11-2021		03	11-2021	
	DOCUMENTS / DATA 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 submitted manufacturer issued by concerned regulatory authority of country of origin.						
3.		nents for the procuren (in case of import).	nent of API with appro	val from	Not provided		
4.	respec		romatograms, Raw dat			tted analytical record for	
5.		liance Record of HPLes on product testing	C software 21CFR & a	udit trail	compliance for th	ted certificate of 21 CFR te HPLC system along with for product testing.	
6.			er for temperature and l bers (real time and acco		logger for ten	ted record of digital data nperature and humidity eal time and accelerated rs.	
		valuator:					
Sectio				servation			
1.6.5	•		GMP certificate of AP nd should be inforce til		acturer issued by	Regulatory Authority of	
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 					
	•					formulation when sodium	
			present in your formulation as preservative. he amount of ethanol in your formulation due to Sorbitol L.				
3.2.P.2							
3.2.P.	² •	• Please justify that why Pharmaceutical equivalence studies have been performed against a local brand instead of brand leader / Innovator brand?					
					in vour formulat	ion or 000% to 1100% for	
	•	• 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 v	why limits of pH for d d contains limits of pH			3.6 - 4.6 while the USP	
3.2.P.:	5 •					he composition of mobile	
		phase provided in U	SP pharmacopeia?	_			
	• Please clarify that why calculation formula mentioned in your CTD is different from the calculation formula given in USP specifications?						
3.2.P.			ocuments /information	of these s	ections as missing	g in the dossiers you have	
3.2.P.		submitted.					
3.2.P.3	, · · · · · · · · · · · · · · · ·						
	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 # u						
	in batch manufacturing, date of initiation of testing.						
	ii. Chromatograms along with raw data.						
			s which should have es tions, formula of calcu	_		eight in mg/gm of sample ations etc.	
	•	Please submit DRA	P clearance documents	for API i	mport.		

• 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 1/s Caraway Pharmaceuticals (DML # 000629) Rawat Central Licensing Board in its 287 th meeting held on 24 th 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			
	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			
	<u> </u>	Firm has submitted QOS as per WHO QOS-PD template. Firm has			

	Module-III (Drug Substance): Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III (Drug Product):		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.			
			structure descripti analytica of speci	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.		
			Accelerated stability Data for 6 months. Temperature: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $75\% \pm 5\%$ RH Real time stability data for 36 months. Temperature: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $65\% \pm 5\%$ RH			
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.			
	Pharmaceutical Equiva Comparative Dissolution		Reference product: Neo-Antial 0.5 mg/mL Syrup Manufactured by: M/s Sami Pharmaceuticals karachi Testing Parameters: Innovator Specifications			
	Analytical validation/verification of		Firm has submitted analytical method validation study reports for drug substance as well as drug product.			
		S'.	FABILIT	Y STUDY DATA		
Manufa	cturer of API			PI 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-0042	22			
_	ner closure system)	PET BOTTI	LE			
			$80^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ l: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Period Real time: 0 Accelerated		06 months I: 06 months				
Frequer			: 0, 3, 6 (Months) 0, 3, 6, 9, 12 (Months)			
	Batch No. DISTO		001	DIST002	DIST003	
	Batch Size	1000 Bo	ottles	1000 Bottles	1000 Bottles	
N	Manufacturing Date	01/20	23	01/2023	01/2023	
	Date of Initiation	13-01-2	.023	13-01-2023	13-01-2023	
	No. of Batches		03			
	DOCUMENTS / DA	TA TO BE	PROVID	ED ALONG WITH STABILI	TY 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.	
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.	
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.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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.

- Tablet (General) Section. ii.
- iii. Capsule (General) Section.
- 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
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $75\% \pm 5\%$ RH Real time stability data for 36 months. Temperature: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $65\% \pm 5\%$ RH
Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing

			excipients validation specificat	s, cor of ions,	process control, process valida atrol of drug product, specificati analytical procedures, batch reference standard or materials	ions, analytical procedures, analysis, justification of	
	Pharmaceutical Equivalence and Comparative Dissolution Profile		Reference Manufact Testing P	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			
	Analytical validation/verification of	method			nitted analytical method valida vell as drug product.	tion study reports for drug	
	varidation/verification of				UDY DATA		
Manuf	acturer of API	Name: Metr Address: Pl	ochem AP ot # 34B,	I Priv	vate Limited, Unit - IV & 60B J.N. Pharma City, T District, Andhra Pradesh, India.	hanam Village, Parawada	
	API Lot No.	PCS-P/2201	2				
	ption of Pack iner closure system)	ALU-ALU leaflet.	Blisters of	3 x	10's further packed in bleech of	eard unit carton along with	
Stabili	ty Storage Condition		al time: 30°C ± 2°C / 65% ± 5%RH ecclerated: 40°C ± 2°C / 75% ± 5%RH				
Time I	Period	Real time: 0 Accelerated	06 months				
Freque	ency		: 0, 3, 6 (Months) 0, 3, 6, 9, 12 (Months)				
	Batch No.	Т	- 01		T- 02	T- 03	
	Batch Size	1200	Tablets		1200 Tablets	1200 Tablets	
	Manufacturing Date	03-	3-2023		03-2023	03-2023	
	Date of Initiation	03-	-2023	03-2023 03-20		03-2023	
	No. of Batches				03		
					LONG WITH STABILITY S	TUDY DATA	
1.	Reference of previous ap with stability study data of			Not	required.		
2.				Sub	mitted		
3.	B. Documents for the procurement of approval from DRAP (in case of import)			Material Loan Giver: Horizon Healthcare Lahore Quantity of Loan: 20 grams			
					antity: 01 kg ed: 15-03-2023		
4.	Data of stability batches will be supp attested respective documents chromatograms, Raw data sheets, COA, data sheets etc.		like	firm	has submitted analytical record	d for product testing.	
5.	Compliance Record of HP audit trail reports on produ		21CFR &		n has submitted certificate of 2 C system along with audit trail		

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

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

- 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		
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $75\% \pm 5\%$ RH Real time stability data for 36 months. Temperature: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $65\% \pm 5\%$ 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 s products.			imilarity between the manufacturer's product and the reference		
				submitted analytical method validation study reports for drug as well as drug product.		
	STABILITY STUDY DATA					
Manufacturer of API Name: Metrochem AF Address: Plot # 34B Mandal, Vishakhapati			ot # 34B, 401	3 & 60B J.N. Ph	arma City, Thanam Village, Parawada	
	API Lot No.	PCS-P/22012	2			
	iption of Pack ainer closure system)	ALU-ALU E leaflet.	Blisters of 3 x	10's further packet	ed in bleech card unit carton along with	
Stabil	ity Storage Condition		$^{\circ}$ C ± $^{\circ}$ C / 65 40 $^{\circ}$ C ± $^{\circ}$ C / 7	% ± 5%RH 75% ± 5%RH		
Time	Period	Real time: 06 Accelerated:				
Frequ	ency		0, 3, 6 (Mont 0, 3, 6, 9, 12 (N			
	Batch No.	T- 04		T- 05	T- 06	
	Batch Size	1200 Tab	olets	1200 Tablets	1200 Tablets	
	Manufacturing Date	03-202	23	03-2023	03-2023	
	Date of Initiation	03-202	22	03-2022	03-2022	
	No. of Batches			03		
	DOCUMENTS / D	ATA TO BE P	ROVIDED A	LONG WITH ST	FABILITY STUDY DATA	
1.	Reference of previous a with stability study data of			t required.		
2.	Approval of API/ DML/ manufacturer issued by authority of country of or	concerned r		omitted		
3.	Documents for the pro approval from DRAP (in			Material Loan Giver: Horizon Healthcare Lahore Quantity of Loan: 20 grams		
				antity: 01 kg ted: 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.			like	n has submitted and	alytical record for product testing.	
5.	Compliance Record of H audit trail reports on production			Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.		
6.	humidity monitoring of time and accelerated)		pers (real ten		record of digital data logger for midity monitoring of real time and hambers.	
	rks of Evaluator:	· · · ·				
Secti		oservations CMP cortific	oto of ADI	R	eply of the firm	
1.0	Please submit GMP certificate of manufacturer issued by regulatory author of the country of origin which should be vill 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	

- 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.

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)
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $75\% \pm 5\%$ RH Real time stability data for 60 months. Temperature: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $65\% \pm 5\%$ RH Naproxen Accelerated stability Data for 6 months. Temperature: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $75\% \pm 5\%$ RH Real time stability data for 60 months. Temperature: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $65\% \pm 5\%$ RH Real time stability data 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.		

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 validation/verification o			submitted analytical methoe as well as drug product.	d validation study reports for drug
	S	TABILIT'	Y 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 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.	Esomep		agnesium Tri-hydrate	Naproxen
			[/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	4	T- 05	T- 06
Batch Size	1200 Ta	blets	1200 Tablets	1200 Tablets
Manufacturing Date	01-202	23	01-2023	01-2023
Date of Initiation	01-02-2	023	01-02-2023	01-02-2023
No. of Batches			03	
DOCUMENTS / DA	ATA TO BE I	PROVIDE	ED ALONG WITH STABI	LITY STUDY DATA
1. Reference of previous a with stability study data of			Not required.	
2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulator authority of country of origin.				
3. Documents for the procurement of API wit approval from DRAP (in case of import).			Material Loan Giver: Wi Quantity of Loan: 200 gra Quantity: 150 kg	Magnesium Tri-Hydrate nbrains Research Laboratories ams
			Dated: 31-10-2022	

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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 (06 th 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 6 th month stability and not performed by same analyst, so the name was not mentioned. Next time we will work on it.

- 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 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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $75\% \pm 5\%$ RH Real time stability data for 60 months. Temperature: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $65\% \pm 5\%$ RH Naproxen Accelerated stability Data for 6 months. Temperature: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $75\% \pm 5\%$ RH

		Temperat	stability data for 60 months are: 30°C ± 2°C : 65% ± 5% RH		
Module-III (Drug Produc			ion, pharmaceutical develop and process control, proces s, control of drug product, sp n of analytical procedures	product including its description, ment, manufacture, manufacturing s validation protocols, control of ecifications, analytical procedures, batch analysis, justification of materials, container closure system	
Pharmaceutical Equiv Comparative Dissolution		Manufac	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		
Analytical validation/verification of			submitted analytical method as well as drug product.	l validation study reports for drug	
	S	TABILITY	Y STUDY DATA		
	ot No. 62 LAPUR (M ty: 26-09-2 s Laborato	M), MEDCHAL (DIST), INI 2025 Naproxen Dires Limited DIVIS/303, Divi Towers, Cyb NDIA.	PHASE-I, I.D.A, JEEDIMETLA, DIA. ber Hills, Gachibowli, Hyderabad –		
API Lot No.	Esomep	razole Ma	agnesium Tri-hydrate	Naproxen	
		ESM	/2210436	2-M-C-3541022	
Description of Pack (Container closure system)	ALU-ALU leaflet.	Blisters of	1 x 10's further packed in	bleech card unit carton along with	
Stability Storage Condition			/ 65% ± 5%RH C / 75% ± 5%RH		
Time Period	Real time: 0 Accelerated		ıs		
Frequency Accelerated: Real Time: (,		
Batch No. T- 01		1	T- 02	T- 03	
Batch Size 1200 Tab		blets	1200 Tablets	1200 Tablets	
Manufacturing Date 01-202		23	01-2023	01-2023	
Date of Initiation 01-02-2		023	01-02-2023	01-02-2023	
No. of Batches			03		
DOCUMENTS / DA	TA TO BE I	PROVIDE	D ALONG WITH STABI	LITY STUDY DATA	
Reference of previous apwith stability study data or			Not required.		

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			
3.			es	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		alytical record for product testing	Ţ.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		ertificate of 21 CFR compliance with audit trail report for product t	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (reatime and accelerated)		midity monitoring of real tim	
Rema	irks of Evaluator:			
Secti	ion Observations		Reply of the firm	
3.2.1	 Please submit manufacturing process as tablet formulation, enteric coatings, drug coating as explained in your master form 	layer coating and film	Submitted	

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 (06 th 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 6 th month stability and not performed by same analyst, so the name was not mentioned. Next time we will work on it.

- 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
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $75\% \pm 5\%$ RH Real time stability data for 12 months. Temperature: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $65\% \pm 5\%$ RH
Module-III (Drug Product):	Firm has submitted data of drug product including its description,

	Pharmaceutical Equiv	alence and	process a excipient validation specificat and stabil	and process control, process s, control of drug product, spec n of analytical procedures, tions, reference standard or ma	ent, manufacture, manufacturing validation protocols, control of cifications, analytical procedures, batch analysis, justification of tterials, container closure system	
	Comparative Dissolution		Manufacture Testing I	Manufactured by: A.Menarini, Italy Testing Parameters: Innovator Specifications Comparative Dissolution Profile Firm has submitted comparative dissolution profile in three mediums		
			products.	similarity between the manufac	cturer's product and the reference	
	Analytical validation/verification of			submitted analytical method as well as drug product.	validation study reports for drug	
		S	FABILIT	Y STUDY DATA		
Manuf	facturer of API	Address: U	nit-IV, Plo	PI Private Limited, Unit - IV ot No. 34B, 40B & 60B, J.N. sakhapatnam District, Andhra	Pharma City, Thanam Village, Pradesh, 531021, India (IND).	
	API Lot No.	CUB-P/220	02			
1	ption of Pack niner closure system)	ALU-ALU leaflet.	Blisters of	1 x 10's further packed in blo	eech card unit carton along with	
Stabili	ty Storage Condition			/ 65% ± 5%RH °C / 75% ± 5%RH		
Time l	Period	Real time: 0 Accelerated		ıs		
Freque	ency	Accelerated Real Time:				
	Batch No.	T- 0	1	T- 02	T- 03	
	Batch Size	1200 Ta	blets	1200 Tablets	1200 Tablets	
	Manufacturing Date	08-20	23	08-2023	08-2023	
	Date of Initiation	26-08-2	.023	26-08-2023	26-08-2023	
	No. of Batches			03		
	DOCUMENTS / DA	ATA TO BE I	PROVIDE	ED ALONG WITH STABILI	TTY STUDY DATA	
1.	Reference of previous apwith stability study data o	f the firm (if a	ny)	•		
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: Weth Quantity of Loan: 500 gram		
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		II -	record for product testing.			
5.	Compliance Record of HI audit trail reports on production		21CFR &		e of 21 CFR compliance for the it trail report for product testing.	

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

Section	Observations	Reply of the firm
	• 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
3.2.P.3	• 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 (06 th month).	Submitted

- 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.

regi	stration 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
	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

	As per SRO		
	As per SRO		
gulatory	MHRA approved formulation		
o status)	N/A		
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). GMP Validity: 07-05-2027		
Overall	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.		
nce):	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.		
	Accelerated stability Data for 6 months. Temperature: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $75\% \pm 5\%$ RH Real time stability data for 12 months. Temperature: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $65\% \pm 5\%$ RH		
et):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
	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.		
method			
S	FABILITY STUDY DATA		
Address: Ui	ochem API Private Limited, Unit - IV nit-IV, Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Iandal, Visakhapatnam District, Andhra Pradesh, 531021, India (IND).		
CUB-P/2200	02		
ALU-ALU leaflet.	Blisters of 1 x 10's further packed in bleech card unit carton along with		
	Overall Substance of Stability alence and Profile method product Since Sin		

Stability Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / \text{Accelerated: } 40^{\circ}\text{C} \pm 2^{\circ}\text{C}$				
Time Period Real time: 06 months Accelerated: 06 month				
Frequ	ency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6, 9,	The state of the s	
	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 / DA	TA TO BE PROVID	ED ALONG WITH STABILI	TTY STUDY DATA
1.	Reference of previous apwith stability study data or		Not required.	
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).			Material Loan Giver: Weth Quantity of Loan: 500 gram	
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.				record for product testing.

Compliance Record of HPLC software 21CFR & Firm has submitted certificate of 21 CFR compliance for the

accelerated stability chambers.

HPLC system along with audit trail report for product testing.

Firm has submitted record of digital data logger for

temperature and humidity monitoring of real time and

Remarks of Evaluator:

time and accelerated)

6.

Section	Observations	Reply of the firm
1.1	• As Bilatine Orodispersible Tablet is not yet marketed in Pakistan therefore	Submitted
	please submit the differential fee of PKR 45000/- for the status of your	Slip # 191325873
	application as New Drug Application.	Dated: 04-03-24
3.2.P.1	• The Module III submitted belongs to drug product Bilastine 20 mg Film	
То	coated tablet while the product applied is Orodispersible tablet 10 mg. please	Submitted
3.2.P.3	submit Module III for Orodispersible 10 mg tablet.	
3.2.P.8	• Please submit stability data of three batches both for accelerated as well as	Submitted
	long term conditions for the last interval (06 th month).	Submitted

Decision: Approved with Innovator's specifications.

audit trail reports on product testing

Record of Digital data logger for temperature and

humidity monitoring of stability chambers (real

- 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.

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
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.	Sodium Chloride, Potassium Chloride, Trisodium citrate dihydrate Name: Rasino herbs (Pvt.) Ltd. Address: N-2, MIDC, Chemical Zone Kupwad, Sangli 416436, Maharastra – India. GMP validity: 20-02-2024 Glucose Anhydrous 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	
	Troume III (Brug buesiume	- /·	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 St	ubstance	Sodium Chloride	
	(Conditions & duration of	f Stability	Accelerated stability data for 06 months	
	studies)		Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{ RH}.$	
			Real time stability data for 60 months	
			Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{ RH}$	
			Glucose Anhydrous	
			Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH.	
			Real time stability data for 36 months	
			Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{ RH}$	
			Potassium Chloride	
			Accelerated stability data for 06 months	
			Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{ RH}$.	
			Real time stability data for 60 months	
			Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{ RH}$	
			Trisodium Citrate di-hydrate	
			Accelerated stability data for 06 months	
			Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{ RH}$.	
			Real time stability data for 60 months	
			Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{ RH}$	
	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 Equivale		` ′	
	Comparative Dissolution Pr	rofile	Manufactured by: Axis Pharmaceuticals.	
			Testing Parameters: BP Specification	
	Analytical method		Firm has submitted analytical method validation study reports for drug	
	validation/verification of product		substance as well as drug product.	
STA		STA	ABILITY STUDY DATA	
Manufact	Manufacturer of API Sodi		um Chloride, Potassium Chloride, Trisodium citrate dihydrate	
			sino herbs (Pvt.) Ltd.	
		Address:	s: N-2, MIDC, Chemical Zone Kupwad, Sangli 416436, Maharastra –	
		India.	-	
	GMP valid		dity: 20-02-2024	
			Glucose Anhydrous	
			eifang Shengtai Medicine Co., Ltd	
			The east of Changda Road, Development District Changle County,	
		China.		
	API Lot No.	China. GMP vali	The east of Changda Road, Development District Changle County, dity: 16-12-2024 119, KP22107, SCP22003, 20230225-1	

	Description of Pack (Container closure system) White colored free flowing granules sachet packed in 1 x 20"s Cardboard					vor filled in aluminum foil
Stabi	lity Storage	y Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$				
Time	Period		Real time: 06 months Accelerated: 06 months			
Frequ	uency		Accelerated: 0, 3, 6 (Mon Real Time: 0, 3, 6, 9, 12 ()	
	Ba	tch No.	OR-01		OR-02	OR-03
	Ba	tch Size	42 Sachet		42 Sachet	42 Sachet
	Manufa	cturing Date	June - 2023	J	une - 2023	June - 2023
	Date of	of Initiation	26/06/2023	2	26/06/2023	26/06/2023
	No. o	of Batches			03	
	DO	CUMENTS / DATA	A TO BE PROVIDED ALC	ONG W	ITH STABILITY S	STUDY DATA
1.		ace of previous appata of the firm (if an	roval of applications with s y)	stability	Submitted	
2.	* *		MP certificate of API manu cory authority of country of		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			-03-2023 um Chloride -03-2023 sium Chloride -03-2023 edium Citrate -03-2023		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.				ed analytical record for	
5.	_	Compliance Record of HPLC software 21CFR & audit trail Submitted reports on product testing				
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) Firm has submitted record of digital logger for temperature and huminonitoring of real time and accelerated stability chambers.				perature and humidity al time and accelerated	
Rema	arks of Eva	aluator:	O1			D 1 6/1 0
	Section	Dlagge submit	Observations GMP certificate API manufacture A	facturer	"Waifang Shanatai	Reply of the firm
	1.6.5	Medicine Co.	Ltd" issued by regulatory au be valid till date.			
	3.2.P.8					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.

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 29 th October 2024.
Evidence of approval of manufacturing facility	Central Licensing Board in its 284 th meeting held on 16 th 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	
product	☐ Export sale ☐ Domestic and Export sales
Dy No and data of submission	•
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
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.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III (Drug Product):		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.			
			Climatic cond Real time stat	litions: 40 oility data	ata for 06 months 0°C ± 2°C / 75% ± a for 36 months 0°C ± 2°C / 65% ±	
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.			
	Pharmaceutical Equivale Comparative Dissolution F		Manufacture	ed by: Re	Nepanac Ophthalmi mington Pharma. Innovator Specifica	•
	Analytical validation/verification of p		Firm has subraubstance as v			dation study reports for drug
		STA	ABILITY STU	DY DAT	TA	
Manufa	cturer of API		naoxing Zhongchang Scientific Co, Ltd Shangyu Chemical Zone, Zhejiang, China.			
	API Lot No.	20220501				
	tion of Pack ner closure system)					zed Dropper Bottle equipped t carton along with Leaflet.
Stability	y Storage Condition		: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ ed: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Time Po	eriod		: 06 months ed: 06 months			
Frequer	ncy		ed: 0, 3, 6 (Months) e: 0, 3, 6, 9, 12 (Months)			
	Batch No.	Т	Γ-002	T-003		T-004
	Batch Size	192	2 bottles	1	192 bottles	192 bottles
	Manufacturing Date	09	-2022		09 -2022	09 -2022
	Date of Initiation	29-0	09-2022	2	9-09-2022	29-09-2022
	No. of Batches				03	
	DOCUMENTS / DATA			T	STUDY DATA	
1.	Reference of previous approstudy data of the firm (if any	olications with	ications with stability Submitted			
2.	2. Approval of API/ DML/GMP certificate issued by concerned regulatory authority					
3.	Documents for the procured DRAP (in case of import).	PI with approv	oroval from Clearance date: 08-06-2022 Quantity: 100 grams			
4.	Data of stability batches will documents like chromatog summary data sheets etc.			ctive firm has submitted analytical record for product testing.		

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

Section	Observations	Reply of the firm		
	Please justify that why manufacturer has chosen	It was attached mistakenly. Firm has		
	sterilising the nepafenac mixture in autoclave while	submitted revised method of manufacturing		
	it is a heat sensitive active ingredient?	according to the nature of product.		
2202	Please justify that why the "milling" of Nepafenac	We are using API having particle size less		
3.2.P.2	to ensure uniform particle size in the suspension	than 10 microns in our formulation. COA is		
	formulation, has not been considered a major step in	attached for reference.		
	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). Please submit COA of API Lot used in			
	pharmaceutical development & manufacturing of stability batches issued by both API supplier as well	Submitted		
	as drug product manufacturer.			
	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	Firm has submitted revised COA of finished		
	while it is a major test in innovator specification	product including all analylytical test as per		
	because a decrease in product viscosity was	innovator specifications.		
	observed with time during storage.			
3.2.P.8	Please submit the stability data sheets containing all			
3.2.1.0	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	Submitted		
	of sodium edetate (HPLC), pH (Ph.Eur.), osmolality			
	(Ph.Eur.), redispersibility, viscosity (Ph.Eur.),			
	particle size (light diffraction), fill volume and			
	sterility (Ph.Eur.).			
	Please submit water loss studies protocol and			
	calculation sheets for ratio of water loss at low	Culousitto d		
	humidity testing conditions and alternative testing	Submitted		
	conditions along with printed weights taken from analytical balance.			
	anaryucar barance.			

- 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			

1					
	☐ 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 29 th 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					
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				
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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 Equivale Comparative Dissolution P	Reference product: Nepanac Ophthalmic suspension Manufactured by: Remington Pharma. Testing Parameters: Innovator Specifications				
	Analytical validation/verification of pro-	method oduct	Firm has subm substance as v			dation study reports for drug
	•	STA	ABILITY STU	DY DAT	T A	
Manufac	cturer of API		aoxing Zhongc Shangyu Chem		entific Co, Ltd e, Zhejiang, China.	
	API Lot No.	20220501	-			
_	ion of Pack er closure system)					zed Dropper Bottle equipped t carton along with Leaflet.
Stability	Storage Condition		: 30°C ± 2°C / 65% ± 5%RH ed: 40°C ± 2°C / 75% ± 5%RH			
Time Per	riod		e: 06 months ted: 06 months			
Frequenc	cy		ed: 0, 3, 6 (Months) e: 0, 3, 6, 9, 12 (Months)			
	Batch No.	Г	Γ-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	2	26-10-2022	26-10-2022
	No. of Batches				03	
	DOCUMENTS / DATA	TO BE PR	ROVIDED AL	ONG W	TH STABILITY	STUDY DATA
	Reference of previous approstudy data of the firm (if any)		olications with	stability	Submitted	
	Approval of API/ DML/GM issued by concerned regulator				Submitted	
	Documents for the procurement of API with approval fro DRAP (in case of import).			al from	Clearance date: 08-06-2022 Quantity: 100 grams	
	Data of stability batches will be 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	
	Record of Digital data logger for temperature and humidi 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.	
	s of Evaluator:			1		0.17.01
Sec	Section Observations				Reply of	f the firm

I		
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? 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	It was attached mistakenly. Firm has submitted revised method of manufacturing according to the nature of product. We are using API having particle size less than 10 microns in our formulation. COA is attached for reference.
	size distribution during long term storage). 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. Please submit DRAP Clearance documents for	Submitted Submitted
	procurement of API. 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.
3.2.P.8	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

- 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 29 th October 2024.				
	Evidence of approval of manufacturing facility	Central Licensing Board in its 284 th meeting held on 16 th 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	□ Domestic sale					
product	☐ 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					
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 36 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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 clos	ure syste	m and stability.		
		naceutical Equivale parative Dissolution Pr		Reference product: Rocip Ophthalmic Solution 0.3% Manufactured by: Remington Pharmaceutical(Pvt.) Ltd. Testing Parameters: USP Specifications				
	Analy valida	ytical ation/verification of pr		Firm has subn substance as v		•	idation study reports for drug	
	STABILITY STUDY DATA							
Manu	facturer of	API		s Citi Pharma 3.5 Kilometer,			Nagar, Kasur -55050 Punjab,	
	API	Lot No.	CPH2210	114				
	ription of P ainer closu	ack are system)					opper Bottle equipped with ton along with Leaflet.	
Stabi	lity Storage	e Condition		: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ ed: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$				
Time	Period			: 06 months ed: 06 months				
Frequ	ency			ed: 0, 3, 6 (Moze: 0, 3, 6, 9, 12)		
	Ba	tch No.	7	Γ-006		T-007	T-008	
	Ba	tch Size	1	Liter		1 Liter	1 Liter	
	Manufa	cturing Date	01	-2023		01-2023	01-2023	
	Date of	of Initiation	09-0	01-2023	C	09-01-2023 09-01-2023		
	No. o	of Batches				03		
		CUMENTS / DATA				1	STUDY DATA	
1.	study da	ata of the firm (if any)			•			
2.	* *	al of API/ DML/GMI by concerned regulator				Submitted		
3.		ents for the procurent (in case of import).	nent of A	PI with approv	val from	Clearance date: L Quantity:	ocally procured	
4.	docume	stability batches will bents like chromatogory data sheets etc.					tted analytical record for	
5.	_	ance Record of HPL on product testing	C software	e 21CFR & au	ıdit trail	Submitted		
6.						mperature and humidity real time and accelerated		
Rema	rks of Eva	aluator:						
-	Section 1.3.4	Please submit section	approval i			tion issued after	Reply of the firm Submitted	
_	approval in meeting of Central Licensing Board. 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		
Decis	ion: Appr		i princa w	- 2151103 tukeli II	om unary	cour outunee.		
	rippi	- · • • • • • • • • • • • • • • • • • •						

- 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.

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 284 th 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					
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					

				amorification reference standard contains 1				
		specification, reference standard, container closure system and stability studies of drug substance and drug product.						
				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 (Conditions & duration studies)	Climatic cond Real time stab	itions: 40 oility data	nta for 06 months 0°C ± 2°C / 75% ± for 36 months 0°C ± 2°C / 65% ±				
	Module-III (Drug Produce	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.						
	Pharmaceutical Equiva Comparative Dissolution		Manufacture	Reference product: Zolopat Ophthalmic Solution 0.1%w/v Manufactured by: Remington Pharmaceutical(Pvt.) Ltd. Testing Parameters: USP Specifications				
	Analytical validation/verification of	method product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.					
		STA	ABILITY STU	DY DAT	YA			
Manufa	cturer of API		aoxing Zhongo Shangyu Chem		entific Co, Ltd e, Zhejiang, China.			
	API Lot No.	20211201	-					
	tion of Pack ner closure system)					oper Bottle equipped with on along with Leaflet.		
Stability	Storage Condition		: 30°C ± 2°C / 6 ed: 40°C ± 2°C					
Time Pe	eriod		: 06 months ed: 06 months					
Frequen	су		ed: 0, 3, 6 (Months) e: 0, 3, 6, 9, 12 (Months)					
	Batch No.	Г	Γ-002		T-003	T-004		
	Batch Size	1	Liter		1 Liter	1 Liter		
	Manufacturing Date	11	1-2022		11-2022	11-2022		
	Date of Initiation	27-	11-2022	2	7-11-2022	27-11-2022		
	No. of Batches				03			
	DOCUMENTS / DATA	ROVIDED AL	ONG WI	TH STABILITY	STUDY DATA			
1.	Reference of previous app study data of the firm (if any	olications with stability Submitted						
2.	Approval of API/ DML/GN issued by concerned regulat		API manufacturer Submitted country of origin.					
3.	Documents for the procure DRAP (in case of import).	ement of A	PI with approv					

4.	Data of stability batches will be supported by attested respective	
	documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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.

Section	Observations	Reply of the firm
1.3.4	Please submit section approval letter for ophthalmic section issued	Submitted
1.3.4	after approval in meeting of Central Licensing Board.	
1.5.5	As per your claim of olopatadine as NSAID, please provide	Correction done.
1.3.3	reference.	Antihistamine
	Please provide GMP certificate of API manufacturer issued by	Submitted
1.6.5	regulatory authority of country of origin and should be valid till	
	date.	
	Please submit water loss studies protocol and calculation sheets for	
3.2.P.8	ratio of water loss at low humidity testing conditions and alternative	Submitted
	testing conditions along with printed weights taken from analytical	Submitted
	balance.	

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 29 th 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	
	Pharmaco-therapeutic Grou (API)	p of	Ophthalmological; decongestant and anti-allergic	
	Pharmaceutical form of applied drug		Ophthalmic solution	
	Reference to Finished produspecifications	ıct	USP Specifications	
	Proposed Pack size		Sterile Eye Drops packed in LDPE bottles	
	Proposed unit price		As per SRO	
	The status in reference reguauthorities	latory	USFDA approved formulation Pataday®	
	For generic drugs (me-too s	tatus)	Zolopat Forte Ophthalmic Solution 0.2% (Reg # 069154) Remington Pharmaceutical (Pvt.) Ltd.	
	Name and address manufacturer.	of API	Name: Shaoxing Zhongchang Scientific Co, Ltd Address: Shangyu Chemical Zone, Zhejiang, China. GMP validity: 28-09-2023	
	Module-II (Quality Summary)	Overall	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, gener properties, solubility, physical form, manufacturers, description amanufacturing process and controls, specifications, analytic procedures and its validation, batch analysis and justification specification, reference standard, container closure system are stability studies of drug substance and drug product.	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III (Drug Product): Pharmaceutical Equivalence and Comparative Dissolution Profile Analytical method		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.	
			Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 36 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH	
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
			Reference product: Zolopat Ophthalmic Solution 0.2%w/v Manufactured by: Remington Pharmaceutical(Pvt.) Ltd. Testing Parameters: USP Specifications	
			Firm has submitted analytical method validation study reports for drug substance as well as drug product.	
	.	STA	ABILITY STUDY DATA	
Manufactu			aoxing Zhongchang Scientific Co, Ltd Shangyu Chemical Zone, Zhejiang, China.	
	API Lot No. 20211201			
			orless solution, filled in sterilized Dropper Bottle equipped with Nozzle and cap, further packed in unit carton along with Leaflet.	

Stability Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$				
Time P	eriod	Real time: 06 months Accelerated: 06 months				
Frequency		The state of the s	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	1	1-01-2023	11-01-2023	
	No. of Batches			03		
	DOCUMENTS / DATA	TO BE PROVIDED AL	ONG WI	TH STABILITY S	STUDY DATA	
1.	Reference of previous approstudy data of the firm (if any)		stability	Submitted		
2.	* *	pproval of API/ DML/GMP certificate of API manufacturer sued by concerned regulatory authority of country of origin.				
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.					ted analytical record for	
5.	5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing			Submitted		
6.	Record of Digital data logg monitoring of stability chamb			logger for ten	eal time and accelerated	

Section	Observations	Reply of the firm
1.3.4	Please submit section approval letter for ophthalmic section issued	Submitted
1.5.4	after approval in meeting of Central Licensing Board.	
1.5.5	As per your claim of olopatadine as NSAID, please provide	Correction done.
1.5.5	reference.	Antihistamine
	Please provide GMP certificate of API manufacturer issued by	Submitted
1.6.5	regulatory authority of country of origin and should be valid till	
	date.	
	Please submit water loss studies protocol and calculation sheets for	
3.2.P.8	ratio of water loss at low humidity testing conditions and alternative	Submitted
	testing conditions along with printed weights taken from analytical	Submitted
	balance.	

- 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.
		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 29 th 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. 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	Each ml contains:
Active Pharmaceutical ingredient	Levofloxacin hemihydrate equivalent to
(API) per unit	Levofloxacin
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

	Module-III (Drug Product): Pharmaceutical Equivalence and Comparative Dissolution Profile		Real time stab	ility data	ions: 40°C ± 2°C / 75% ± 5% RH. ity data for 36 months ions: 30°C ± 2°C / 65% ± 5% RH		
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.				
			Manufacture	Reference product: Zolopat Ophthalmic Solution 0.2% w/v Manufactured by: Remington Pharmaceutical(Pvt.) Ltd. Testing Parameters: USP Specifications			
	Analytical validation/verification of pro-		Firm has subm substance as w			dation study reports for drug	
		STA	ABILITY STU	DY DAT	'A		
Manufac	cturer of API		aoxing Zhongcl Shangyu Chemi	-	entific Co, Ltd e, Zhejiang, China.		
	API Lot No.	20211201					
	ion of Pack ner closure system)					oper Bottle equipped with on along with Leaflet.	
Stability	Storage Condition		: 30°C ± 2°C / 65% ± 5%RH ed: 40°C ± 2°C / 75% ± 5%RH				
Time Pe	riod		: 06 months ed: 06 months				
Frequenc	cy		ed: 0, 3, 6 (Months) :: 0, 3, 6, 9, 12 (Months)				
	Batch No.	Γ	Γ-003		T-004	T-003	
	Batch Size	1	Liter		1 Liter	1 Liter	
	Manufacturing Date	01	1-2023		11-2022	11-2022	
	Date of Initiation	11-0	01-2023	1	1-01-2023	11-01-2023	
	No. of Batches				03		
	DOCUMENTS / DATA	TO BE PR	ROVIDED ALC	ONG WI	TH STABILITY	STUDY DATA	
	Reference of previous approstudy data of the firm (if any)		olications with	stability	Submitted		
	Approval of API/ DML/GM issued by concerned regulator	y authority	y of country of o	origin.	Submitted		
	Documents for the procurer DRAP (in case of import).	PI with approv	al from	Clearance date: 200 grams Quantity: 08-06-2022			
	Data of stability batches will documents like chromatogrammary data sheets etc.	•	•		ted analytical record for		
	Compliance Record of HPL reports on product testing	C software	e 21CFR & au	dit trail	Submitted		
	Record of Digital data logg monitoring of stability chamb				Firm has submitted record of digital da logger for temperature and humidi monitoring of real time and accelerat stability chambers.		

narks 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		
2200	• 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		
3.2.P.8	• 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.

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 29 th 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)	
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	

	~		4 070	
	Proposed unit price		As per SRO	
	The status in reference regulauthorities	latory	MHRA approved formulation	
	For generic drugs (me-too s	status)	Moxian Eye drops by Barrett	
Name and address of manufacturer.		of API	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 Summary)	Overall	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	e):	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 Su (Conditions & duration of studies)		Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 48 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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 Equivale Comparative Dissolution Pr		Reference product: Moxigan 0.5% w/v Eye Drops Manufactured by: Remington Pakistan Testing Parameters: USP Specifications	
	Analytical validation/verification of pr	method oduct	Firm has submitted analytical method validation study reports for drug substance as well as drug product.	
		STA	ABILITY STUDY DATA	
Plot No 9.		Plot No 9	Pharmaceuticals, ,10,11 Milan Industrial Estate, Santej, Ta: Kalol, Dist: Gandhinagar - Gujarat, India	
API Lot No. MOX201		MOX2013	30	
			orless solution, filled in sterilized Dropper Bottle equipped with Nozzle and cap, further packed in unit carton along with Leaflet.	
			: 30°C ± 2°C / 65% ± 5%RH ed: 40°C ± 2°C / 75% ± 5%RH	
			: 06 months ed: 06 months	
·			ed: 0, 3, 6 (Months) e: 0, 3, 6, 9, 12 (Months)	

	В	atch No.	T-006		T-007	T-008	
	Batch Size 192 bottles 192 bot			192 bottles	192 bottles		
	Manufa	acturing Date	Date 01-2023 01-2023				
	Date	of Initiation	09-01-2023 09-01-2023 09-01-2023			09-01-2023	
	No.	of Batches			03		
	DO	CUMENTS / DATA	TO BE PROVIDED AL	ONG W	TH STABILITY	STUDY DATA	
1.		nce of previous appro lata of the firm (if any)	val of applications with	stability	Submitted		
2.			P certificate of API man ry authority of country of		Submitted		
3.		ents for the procurent (in case of import).	nent of API with approval from Clearance date: 200 grams Quantity: 08-06-2022				
4.	docum		I be supported by attested respective grams, Raw data sheets, COA, product testing.			for	
5.		iance Record of HPL on product testing	C software 21CFR & audit trail Submitted				
6.			ogger for temperature and humidity mbers (real time and accelerated) Firm has submitted record of digital of logger for temperature and humi monitoring of real time and accelerated stability chambers.			nidity	
Rema	arks of Ev	aluator:				.	7
	Section Observations				Reply of the firm	_	
	3.2.P.8	of water loss at lov	r loss studies protocol and w humidity testing condit with printed weights taken	ions and	alternative testing	Submitted	
		Please submit API	procurement documents	approved	by DRAP.	Submitted	

- 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 29 th 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)
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 48 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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		•	dation study reports for drug		
validation/verification	validation/verification of product substance as well as drug product.				
Manufacturer of API FLAX LABORATORIES PRIVATE LIMITED					
Wandracturer of AFT		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			pper Bottle equipped with		
(Container closure system)		further packed in unit cart	on along with Leaflet.		
Stability Storage Condition		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Period	Real time: 06 months Accelerated: 06 months				
Frequency	Accelerated: 0, 3, 6 (Mon Real Time: 0, 3, 6, 9, 12 (
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 / I	DATA TO BE PROVIDED ALO	NG WITH STABILITY	STUDY DATA		
1. Reference of previous study data of the firm	s approval of applications with s (if any)	stability Submitted			
	IL/GMP certificate of API manufegulatory authority of country of o				
3. Documents for the p DRAP (in case of imp	rocurement of API with approva		from Quantity: 1 kg Dated: 12-05-2022		
	es will be supported by attested resonatograms, Raw data sheets, etc.		tted analytical record for		
•	of HPLC software 21CFR & aud	dit trail Submitted			
	ta logger for temperature and he chambers (real time and accelerate	logger for ter	mperature and humidity real time and accelerated		
Remarks of Evaluator:	01 (1	D 1 64	1 0		
Section • Please subr	Observations nit water loss studies protocol and	Reply of t	ne iirm		
calculation low hum alternative	alternative testing conditions along with printed weights taken from analytical		tted		
Please sub- approved b	mit API procurement documents y DRAP.	Submi	tted		
Please submit calculation for assay of drug product as per calculation formula provided in official monograph.		Submi	tted		
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.

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 29 th 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)		
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		

3.	Documents for the procured DRAP (in case of import).	ment of A	PI with approv	val from	Quantity: 1 kg Dated: 12-05-202	2	
2.	Approval of API/ DML/GM issued by concerned regulato	y of country of	origin.				
1.	Reference of previous approstudy data of the firm (if any)						
	DOCUMENTS / DATA				T	STUDY DATA	
	No. of Batches				03		
	Date of Initiation	12-0	01-2023	1	2-01-2023	12-01-2023	
	Manufacturing Date	-	1-2023		01-2023	01-2023	
	Batch Size	192	2 bottles	1	92 bottles	192 bottles	
	Batch No.	Г	Γ-002		T-003	T-004	
Frequer	ncy			ed: 0, 3, 6 (Months) e: 0, 3, 6, 9, 12 (Months)			
Time Po	eriod		: 06 months ed: 06 months				
	y Storage Condition	Real time	: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ ed: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$	55% ± 5%	SRH		
	tion of Pack ner closure system)					pper Bottle equipped with on along with Leaflet.	
	API Lot No.	TIM/22/0	01				
Manufa	cturer of API		ORATORIES PRI 1IDC Mahad, Bi			laharashtra, India-402301	
			ABILITY STU				
	Analytical validation/verification of p		substance as v	Firm has submitted analytical method validation study reports for drug substance as well as drug product.			
	Pharmaceutical Equivale Comparative Dissolution P		Manufacture	ed by: Re	Blotim Ophthalmic mington Pakistan USP Specifications		
	Module-III (Drug Product):		composition, manufacturing protocols, con analytical pro analysis, justin	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.			
	Stability Studies of Drug S (Conditions & duration of studies)	Climatic cond Real time stat	litions: 40 oility data	ata for 06 months $0^{\circ}C \pm 2^{\circ}C / 75\% \pm 1$ a for 48 months $0^{\circ}C \pm 2^{\circ}C / 65\% \pm 1$			
			nomenclature manufacturers specifications and justificati	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.			
			specification, reference standard, container closure system and stability studies of drug substance and drug product.				

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	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.

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.	

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 Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.
	M/s Shrooq Pharmaceuticals Pvt Ltd. (DML # 000577) 21km Ferozpur Road Lahore.
	☑ Manufacturer☐ Importer☐ Is involved in none of the above (contract giver)
	GMP Certificate of the firm issued on the basis of inspection report dated 29 th October 2024.
Evidence of approval of manufacturing facility	New Section
	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
product	 □ Domestic sale □ Export sale ☑ Domestic and Export sales
Dy. No. and date of submission	Dy. No. J7L-Z8J-VHYH dated 22-03-2024
	PKR 30,000/-: Dated 30-05-2023 Slip # 428326618
The proposed proprietary name / brand name	KENVID eye drops 0.3 % w/v
	Each ml contains: Ofloxacin
	Ophthalmologicals, anti-infectives, fluoroquinolones ATC code: S01AE01
Pharmaceutical form of applied drug	Ophthalmic solution
Reference to Finished product specifications	USP Specification

			Sterile Eye Drops packed in LDPE bottles			
	Proposed unit price		As per SRO			
	The status in reference regulauthorities	latory	MHRA approved formulation			
For generic drugs (me-too status)			Ciof Eye drops by Remingtion Pakistan			
	Name and address 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 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	e):	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 Su (Conditions & duration of studies)		Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 60 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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 Equivaler Comparative Dissolution Pr		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.			
		STA	ABILITY STUDY DATA			
Manufactu	Plot No. E		ARTI DRUGS LTD. – 120/119/105/106/104, M.I.D.C., Tarapur, Boisar, Tal. – Palghar, ne - 401 506. Maharashtra, INDIA			
	API Lot No.	OPC/1209	90662			
Descriptio (Container	n of Pack closure system)		orless solution, filled in sterilized Dropper Bottle equipped with Nozzle and cap, further packed in unit carton along with Leaflet.			
Stability S	, ,		: 30°C ± 2°C / 65% ± 5%RH ed: 40°C ± 2°C / 75% ± 5%RH			
Time Perio	bod		: 06 months ed: 06 months			

Frequency)				
В	Batch No.	T-002		T-003	T-004	
В	atch Size	192 bottles	1	192 bottles	192 bottles	
Manuf	facturing Date	09-2022		09-2022	09-2022	
Date	of Initiation	02-09-2022	0	2-09-2022	02-09-2022	
No.	of Batches			03		
DC	OCUMENTS / DATA	TO BE PROVIDED AL	ONG WI	TH STABILITY S	ΓUDY DATA	
	ence of previous approduta of the firm (if any)	oval of applications with	stability	Submitted		
		P certificate of API man ry authority of country of		Submitted		
	nents for the procurer (in case of import).	ment of API with appro-	Quantity: 50 kg Dated: 12-03-2022			
docum		be supported by attested re rams, Raw data sheets			d analytical record fo	
	liance Record of HPL s on product testing	.C software 21CFR & a	udit trail	Submitted		
	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 E	valuator:	Observations				
Section			Reply of the firm			
3.2.P.8	 Please submit wat of water loss at lo conditions along w 	l alternative testing	Submitted			
	Please submit API procurement documents approved by DRAP. Submitted					

- 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 29 th October 2024.	
	Evidence of approval of manufacturing facility	New Section	
		☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)	
	Intended use of pharmaceutical	☐ Domestic sale	

product	D Francis and			
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			
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 60 months Climatic conditions: ${^{\circ}\text{C}} \pm 25^{\circ}\text{C} / 60\% \pm 5\%$ 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			

		ytical lation/verification of pr		Firm has subn		•	idation study reports for	drug
		1		BILITY STU		0 1		
Man	ufacturer o	f API	, ,	anju Pharmad ngxi Road, Mo		o, Ltd ustrial Park, Xianjı	ı Zhejiang, China	
	AP	I Lot No.	P101-22020	03				
	ription of l tainer clos	Pack ure system)					opper Bottle equipped ton along with Leaflet.	with
Stabi	lity Storag	e Condition		$30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ d: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$				
Time	Period		Real time: (06 months d: 06 months				
Frequ	uency			d: 0, 3, 6 (Mo: 0, 3, 6, 9, 12	,)		
	В	atch No.	T-	002		T-003	T-004	
	Ва	atch Size	294 t	oottles	2	94 bottles	294 bottles	
	Manuf	acturing Date	08-2	2023		08-2023	08-2023	
	Date	of Initiation	30-08	3-2023	30-08-2023		30-08-2023	
	No.	of Batches				03		
	DO	CUMENTS / DATA	TO BE PRO	OVIDED AL	ONG WI	TH STABILITY	STUDY DATA	
1.		nce of previous approlata of the firm (if any)		ications with	stability	Submitted		
2.		val of API/ DML/GM by concerned regulator						
3.		nents for the procurer (in case of import).	nent of API	I with approv	val from	Quantity: 500 grams Dated: 30-05-2022		
4.	docum	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA summary data sheets etc.					tted analytical record	for
5.	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)					logger for te	tted record of digital mperature and hum real time and accele s.	nidity	
Rem	arks of Ev	aluator:						1
-	Section 3.2.S.7	Please submit state requirement.	Observations pility data of API according to Zone IV-A		e IV-A	Reply of the firm Submitted		
	Please submit water loss studies protocol and calcuration of water loss at low humidity testing condition testing conditions along with printed weights taken			conditions	s and alternative	Submitted		

balance.

• 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.

• Please submit API procurement documents approved by DRAP.

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

Submitted

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)

Liquid Injectable Vials SVP (General) in place of Intravenous infusion-LVP (General / Antibiotics)				
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			
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,			

Module-III (Drug Substance): Firm has submitted drug product, specifications, analytical procedures, and controls, specifications, analytical process and process and process and composition, phase and stability studies of Drug Substance (Conditions & duration of Stability Studies of Drug Substance): Accelerated stability Data for 6 months. Temperature: 40°C = 2°C Humidity: 75% = 59% RH Real time: 30°C = 2°C Humidity: 30°C = 2°C Humidity: 30°C = 30°C Humidity: 30°C Humidity: 30°C = 30°C Humidity: 30°C Humidity: 30°C Humidity: 30°C							
Stability Studies of Drug Substance (Conditions & duration of Stability Studies) Accelerated stability studies of Drug Substance (Conditions & duration of Stability studies) Accelerated stability Data for 6 months.							
Conditions & duration of Stability Studies Studies			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				
Composition, pharmaceutical development, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile method Manufactured by: Sanofi Testing Parameters: BP Specifications	(Conditions & duration	(Conditions & duration of Stability studies) Module-III (Drug Product):		Temperature: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $75\% \pm 5\%$ RH Real time stability data for 36 months. Temperature: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Comparative Dissolution Profile	Module-III (Drug Produc			composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system			
Validation/verification of product Substance as well as drug product. STABILITY STUDY DATA	_	*		Manufactured by: Sanofi			
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) 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 Accelerated: 06 months Real Time: 0, 3, 6, (Months) Real Time: 0, 3, 6, 9, 12 (Months) Batch No. T-001 T-02 T-03 Batch Size S00 bottles S00 bottles Manufacturing Date 01-2023 01-2023 01-2023 01-2023 Date of Initiation 20-01-2023 20-01-2023 No. of Batches DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA 1. Reference of previous approval of applications Not required.							
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) 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 Not required.	·	S	TABILITY STU	JDY DATA			
API Lot No. WTZ/1040703 Description of Pack (Container closure system) Stability Storage Condition Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Time Period Real time: 06 months 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 Not required.	Manufacturer of API	Address: Plo India.	ot # 2902 – 2904, 2601 to 2605, 2509, G.I.D.C, Sarigam, Valsad, Guajarat,				
(Container closure system) Stability Storage Condition Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Time Period Real time: 06 months 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 OCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA 1. Reference of previous approval of applications Not required.	API Lot No.	WTZ/10407	03				
Accelerated: 40°C ± 2°C / 75% ± 5%RH Time Period Real time: 06 months Accelerated: 0, 3, 6 (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 No. of Batches 03 DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA 1. Reference of previous approval of applications Not required.	_	LDPE Bottle	es				
Accelerated: 06 months	Stability Storage Condition						
Real Time: 0, 3, 6, 9, 12 (Months) Batch No.	Time Period						
Batch Size 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 Not required.	Frequency			·			
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 Not required.	Batch No. T-		001	T- 02	T- 03		
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 Not required.	Batch Size 500 l		bottles	500 bottles	500 bottles		
No. of Batches DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA Reference of previous approval of applications Not required.	Manufacturing Date 01-		2023	01-2023	01-2023		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA 1. Reference of previous approval of applications Not required.	Date of Initiation	20-0	1-2023	20-01-2023	20-01-2023		
1. Reference of previous approval of applications Not required.	No. of Batches 03						
	DOCUMENTS / DA	TA TO BE I	PROVIDED AL	ONG WITH STABILITY	STUDY DATA		
				equired.			

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

Section	Observations	Reply of the firm
1.6.5	• Please submit GMP certificate of API manufacturer issued by regulatory	Submitted
	authority of the country of origin which should be valid till date.	
3.2.S.7	Please submit stability data of active ingredient climatic condition of Zone Submit stability data of active ingredient climatic condition of Zone	
	IV for long term / real time data.	
3.2.P.8	• Please submit Water loss study data along with calculation sheets and prints	Submitted
	of weighing at each interval.	

- 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		
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $75\% \pm 5\%$ RH Real time stability data for 48 months. Temperature: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $65\% \pm 5\%$ 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-A Address: Coastal Indust					en county, Zhejiang, China.
API Lot No. 220929-1		220929-1			
Description of Pack (Container closure system)		LDPE Bottles			
Stabil	ity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time	Period	Real time: 06 months Accelerated: 06 month	s		
Frequ	ency	Accelerated: 0, 3, 6 (M) Real Time: 0, 3, 6, 9, 1			
	Batch No.	T- 001	T- 002		T- 003
	Batch Size	500 bottles	500 bottle	es	500 bottles
	Manufacturing Date	01-2023	01-2023		01-2023
	Date of Initiation	20-01-2023	20-01-202	23	20-01-2023
	No. of Batches		03		
	DOCUMENTS / D	ATA TO BE PROVIDE	D ALONG WITH ST	ABILITY	STUDY DATA
1.	Reference of previous with stability study data	approval of applications 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.			Material Loan Giver: Medicraft Pharmaceuticals, Hayatabad Quantity: 400 kg Invoice: EXP/225/21-22 Dated: 25-11-2022 Quantity of Loan: 05kg		
4.	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 ana	lytical reco	rd for product testing.
5.	Compliance Record of F audit trail reports on pro-	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.			
6.		ogger for temperature and stability chambers (real	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
	rks of Evaluator:				
3.2.		Observation Vater loss study data along ach interval.		and prints	Reply of the firm 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	☐ 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
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.

(Conditions & duration of Stability studies)		Accelerated stability Data for 6 months. Temperature: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $75\% \pm 5\%$ RH Real time stability data for 48 months. Temperature: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $65\% \pm 5\%$ RH			
Module-III (Drug Prod			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
Pharmaceutical Equ Comparative Dissolution		Manufactur	e: Otsumol infusion er: M/s Otsuka ameters: Innovator Specificati	ons	
Analytical validation/verification	method of product		omitted analytical method valid well as drug product.	dation study reports for drug	
	S	FABILITY S	TUDY DATA		
		ii BBCA Likang Pharmaceutical Co. Ltd. gh & New Technology Industries Development Zone, Bengbu city, Anhui nina.			
API Lot No.	202109103A	A			
Description of Pack (Container closure system)					
Stability Storage Condition		$0^{\circ}\text{C} \pm 2^{\circ}\text{C} / 69$: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 69$	5% ± 5%RH 75% ± 5%RH		
Time Period	Real time: 0 Accelerated				
Frequency		: 0, 3, 6 (Mon 0, 3, 6, 9, 12 (
Batch No.	P	001	P 002	P 003	
Batch Size		bottles	500 bottles	500 bottles	
Manufacturing Date		-2022	04-2022	04-2022	
Date of Initiation	22-0	01-2023 22-01-2023 22-01-2023		22-01-2023	
No. of Batches		03			
			ALONG WITH STABILITY	STUDY DATA	
with stability study data	1. Reference of previous approval of applic with stability study data of the firm (if any)				
2. Approval of API/ DML/GMP certificate manufacturer issued by concerned reauthority of country of origin.			ıbmitted		
3. Documents for the procurement of Al approval from DRAP (in case of import).		Q In Da	taterial Loan Giver: Medicraft uantity: 500 kg tvoice: EXP/225/21-22 ated: 02-12-2021 Quantity of Loan: 05kg	Pharmaceuticals, Hayatabad	

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	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Section	Observations	Reply of the firm
3.2.P.8	Please submit Water loss study data along with calculation sheets and prints	Submitted
	of weighing at each interval.	

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.

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
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.
		As per SRO
		TGA Australia approved formulation
For generic drugs (me-too	status)	N/A
Name and address manufacturer.	of API	Name: Shanghai New Hualian Pharmaceutical Co. Ltd. Address: 217 MINLE ROAD, SHANGAI, HAIWAN, China. GMP Validity: 31-12-2025
Module-II (Quality Summary)	Overall	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 Substar	nce):	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 (Conditions & duration studies)		Accelerated stability Data for 6 months. Temperature: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $75\% \pm 5\%$ RH Real time stability data for 36 months. Temperature: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Humidity: $65\% \pm 5\%$ RH
Module-III (Drug Product	t):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equiva Comparative Dissolution		Reference product: Accutane Soft Gel Capsule 30 mg Manufactured by: JG Pharma Testing Parameters: USP Specifications
*		Firm has submitted analytical method validation study reports for drug substance as well as drug product.
	S	ΓABILITY STUDY DATA
Manufacturer of API		ghai New Hualian Pharmaceutical Co. Ltd. 7 MINLE ROAD, SHANGAI, HAIWAN, China.
API Lot No.		
Description of Pack (Container closure system)	ALU-ALU in a master of	Blister each containing 10s packed din printed unit carton, further packed carton.
Stability Storage Condition		$0^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$
Time Period	Real time: 0	6 months

			Accelerated: 06 month	ıs				
Freque	Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		,			
		Batch No.	TR- 001		TR- 002	TR- 001		
	Batch Size 1.2F				1.2KG	1.2KG		
	Manufacturing Date 10-2022		10-2022		10-2022	10-2022		
	Dat	e of Initiation	28-10-2022		28-10-2022	28-10-2022		
	No	o. of Batches			03			
		DOCUMENTS / DA	TA TO BE PROVIDE	ED A	LONG WITH STABILITY ST	UDY DATA		
1.		erence of previous ap stability study data of	proval of applications the firm (if any)	Not	required.			
2.	man		SMP certificate of API concerned regulatory gin.	Sub	mitted			
3.		uments for the proc roval from DRAP (in c	urement of API with ase of import).		antity: 30 kg ed: 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.		npliance Record of HP t trail reports on produ		Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.				
6.	hum		ger for temperature and tability chambers (real	tem	n has submitted record of of perature and humidity monitoral elerated stability chambers.			
		f Evaluator:						
Secti			Servations	4	Reply of the firm	m		
1.3.	.11	scheme in accorda Packing) Rules, 1 which should	nner (primary)] & col nce with Drug (Labellin 986 along with specim	g & nens of	Submitted			
1.6	Please submit GMP certificate of A manufacturer issued by regulatory author of the country of origin which should be vatill date.		API Submitted					
3.2.	P.2	• Please submit comparative disso	complete record lution profile.	Supmitted				
3.2.	As isotretinoin is a light sensitive mate with high risk of oxidation, please providetails of the arrangement of sodium valamps / other arrangements for opening bulk container of API to protect from light and air.		vide apor g of	Firm has submitted SOP precautionary measures i.e. inclight during manufacturing proc	stallation of red			
	 Please submit details of precautions duridispensing procedure. 		ring	Firm has submitted SOP precautionary measures i.e. inslight during dispensing and contnous nitrogen purging.	stallation of red			

	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.	Submitted	
	 Please submit evidence of helium or nitrogen purging required during preparation of diluent for sample preparation for HPLC assay. 	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	
	Please submit COA of API Lot# used in manufacturing of stability batches.	Submitted	
3.2.P.8	Please Submit DRAP clearance documents for procurement of API.	Submitted	
	• Please submit complete 06 th month stability data for all intervals (0,3 & 6 months).	Submitted	

- 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	
product	□ Export sale☑ Domestic and Export sales
Dv. No. and data of submission	
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	Each soft gelatin capsule contains:
Active Pharmaceutical ingredient (API) per unit	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.
	<u> </u>

	studies) I			Temperature: $25^{\circ}C \pm 2^{\circ}C$ Humidity: $60\% \pm 5\%$ RH Real time stability data for 36 months. Temperature: $5^{\circ}C \pm 3^{\circ}C$				
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.					
	Pharmaceutical Equive Comparative Dissolution	Manufac	Reference product: Accutane Soft Gel Capsule 30 mg Manufactured by: JG Pharma Testing Parameters: USP Specifications					
	Analytical validation/verification of				nitted analytical method valuell as drug product.	idation study reports for drug		
		S'.	FABILITY	Y ST	UDY DATA			
Manu	facturer of API				ian Pharmaceutical Co. Ltd. D, SHANGAI, HAIWAN, (China.		
	API Lot No.							
	Description of Pack (Container closure system) ALU-ALU carton.		Blister of 1's packed in printed unit carton, further packed in a master					
Stabil	ity Storage Condition		$0^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{RH}$: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{RH}$					
Time	Period	Real time: 0 Accelerated		.S				
Frequ	ency			(a), 3, 6 (Months) (b), 3, 6, 9, 12 (Months)				
	Batch No.	TR	L- 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 / DA	TA TO BE I	PROVIDE	D A	LONG WITH STABILITY	Y STUDY DATA		
1.	Reference of previous ap with stability study data of			Not	required.			
2.	Approval of API/ DML/Omanufacturer issued by authority of country of ori	concerned						
3.				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 rec	cord for product testing.		
5.	Compliance Record of HF audit trail reports on produ		21CFR &			of 21 CFR compliance for the rail 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.

	e and accelerated)	celerated stability chambers.		
	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. 	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 275 th meeting.	formulation is available in SRA countries in ampoule, but in Pakistan 200,000 IU is available		
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?			
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? Is the use of amount of overage to compensate for expected and documented manufacturing losses? 	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		
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.		
İ	D1 1 1 1 1 C 1 1 1	C111		

• 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 250^{th} 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 10^{th} product application is mentioned below.

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
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.	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
Module-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

	1				
	Module-III (Drug Substance): Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III (Drug Product):		procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.		
			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.		
	Pharmaceutical Equivale Comparative Dissolution P		Reference product: Calamine Lotion Manufactured by: Jawa Pharma. Testing Parameters: USP Specifications		
	Analytical validation/verification of pr		Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
		STA	ABILITY STUDY DATA		
Address: GLP valid Name: Mo Address: PALAGH		nmol Chemical Private Limited J-63 Road No. U-6, MIDC, Tai lity: 28-09-2023 <u>Calar</u> ehta Pharmaceutical Industries	loja, District Raigad Zone1, India.		
	API Lot No.		Calamine	Zinc oxide	
			CAL/37/2022	AC/23070824	
		viscous lotion packed in 120 ron along with Leaflet	nl dropper further packed in Bleech Card		
, ,		: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ ed: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Peri	iod		: 06 months ed: 06 months		
Frequency	y		red: 0, 3, 6 (Months) e: 0, 3, 6, 9, 12 (Months)		

	Batch No.	т	·-001		T-002	T-003	
	Batch Size		Liter	1	5 Liter	5 Liter	
	Manufacturing Date		01-2023		6 -01-2023	16 -01-2023	
	Date of Initiation	16-0	01-2023	1	6-01-2023	16-01-2023	
No. of Batches					03		
DOCUMENTS / DATA TO BE PROVIDED ALON						STUDY DATA	
1.	Reference of previous approval of applications with stability Submitted study data of the firm (if any)						
2.	Approval of API/ DML/GMP certificate of API manufacturer submitted issued by concerned regulatory authority of country of origin.						
3.	Documents for the procurem DRAP (in case of import).				Calamine: 1.5 kg Zinc Oxide: 1.5 kg		
4.	Data of stability batches will be documents—like—chromatogra summary data sheets etc.					ted analytical record for	
5.	Compliance Record of HPLC reports on product testing	C software	e 21CFR & a	udit trail	Not required		
6.	Record of Digital data logge monitoring of stability chambe		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.				
Remarl	ks of Evaluator:				<u> </u>		
life a • Man regis Central	 Decision: Approved. Manufacturer will place first three production batches on long term stability studies throughout proposed shell 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 						
Licciisc			d on 16th Dece	ember 202			
	(DML) to M/s Wallace Pharma	a Evolutio	d on 16 th Dece n (DML # 000	ember 202 1951), Lah	ore including Inject	etion (Carbapenem) Section.	
608.		a Evolutio nt /	d on 16 th Dece n (DML # 000 M/s Wallace	ember 202 1951), Lah Pharma		etion (Carbapenem) Section. # 000951)	
	Name, address of Applican	a Evolutio at / Holder	d on 16 th Dece n (DML # 000 M/s Wallace Kala Wala S	ember 202 1951), Lah Pharma top, 20-k Pharma E	ore including Injection (DML)	etion (Carbapenem) Section. # 000951) rala Road.	
-	Name, address of Applican Marketing Authorization I	a Evolutio at / Holder	d on 16 th Dece n (DML # 000 M/s Wallace Kala Wala S M/s Wallace Kala Wala Ste ⊠ Manufactu □ Importer	ember 202 1951), Lah Pharma top, 20-k Pharma E op, 20-km	ore including Inject Evolution (DML : m Lahore Jaranw volution (DML # 0	etion (Carbapenem) Section. # 000951) rala Road. 1000951) Road.	
	Name, address of Applican Marketing Authorization I Name, address of Manufactu	a Evolutio at / Holder	d on 16 th Dece n (DML # 000 M/s Wallace Kala Wala S M/s Wallace Kala Wala Ste ⊠ Manufactu □ Importer	ember 202 1951), Lah Pharma top, 20-k Pharma E op, 20-km	ore including Inject Evolution (DML; m Lahore Jaranw volution (DML # 0 n Lahore Jaranwala	etion (Carbapenem) Section. # 000951) rala Road. 1000951) Road.	
	Name, address of Applican Marketing Authorization I Name, address of Manufactu Status of the applicant	a Evolutio It / Holder Iring site.	d on 16th Dece n (DML # 000 M/s Wallace Kala Wala S M/s Wallace Kala Wala Sto ⊠ Manufactu □ Importer □ Is involved	ember 202 1951), Lah Pharma top, 20-k Pharma E op, 20-km	ore including Inject Evolution (DML; m Lahore Jaranw volution (DML # 0 n Lahore Jaranwala	etion (Carbapenem) Section. # 000951) rala Road. 1000951) Road.	
	Name, address of Applicant Name, address of Manufactur Name, address of Manufactur Status of the applicant GMP status of the firm Evidence of approv	a Evolutio It / Holder Iring site.	d on 16th Dece n (DML # 000 M/s Wallace Kala Wala S M/s Wallace Kala Wala Ste ☑ Manufactu ☐ Importer ☐ Is involved New License	Product (Evolution (DML and Lahore Jaranwalan Lahore Jara	etion (Carbapenem) Section. # 000951) rala Road. 1000951) Road.	
	Name, address of Applicant Marketing Authorization I Name, address of Manufactur Status of the applicant GMP status of the firm Evidence of approvemanufacturing facility	a Evolutio It / Holder Iring site. al of	d on 16th Decen (DML # 000) M/s Wallace Kala Wala S M/s Wallace Kala Wala St Manufactu Importer Is involved New License New License New Drug Generic Drug Export sales	Product (crug Product sale	Evolution (DML and Lahore Jaranwalan Lahore (Contra Lahore) Lahore Jaranwalan Lahore (Contra Lahore) Lahore Jaranwalan L	etion (Carbapenem) Section. # 000951) rala Road. 1000951) Road.	
	Name, address of Applicant Marketing Authorization I Name, address of Manufactur Status of the applicant GMP status of the firm Evidence of approvimanufacturing facility Status of application Intended use of pharm	a Evolutio It / Holder Bring site. The site of the	d on 16th Decen (DML # 000) M/s Wallace Kala Wala S M/s Wallace Kala Wala St	Product (rug Pr	Evolution (DML and Lahore Jaranwalan Lahore (Contra Lahore) Lahore Jaranwalan Lahore (Contra Lahore) Lahore Jaranwalan L	etion (Carbapenem) Section. # 000951) rala Road. 1000951) Road.	

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)
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 36 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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 D	ATA			
Manufa	ecturer 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 Steril	White to off White Color Sterile Powder filled in Type I glass vial.			
Stability	y Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm \text{Accelerated}$: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$				
Time Po	eriod	Real time: 06 months Accelerated: 06 months				
Frequer	ncy	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)	hs)			
	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 STABILIT	TY STUDY DATA		
1.	Reference of previous appr study data of the firm (if any	oval of applications with stability)	ty Submitted			
2.		IP certificate of API manufactur ory authority of country of origin.				
3.	Documents for the procure DRAP (in case of import).	ment of API with approval from	om Submitted			
4.		be supported by attested respecti grams, Raw data sheets, CO			rd for	
5.	Compliance Record of HPI reports on product testing	LC software 21CFR & audit tr	ail 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 accelerate stability chambers.					
	ks of Evaluator:					
Sectio		Observations		Reply of the firm		
3.2.S. ²	 Please provided the de and Meropenem salt an 	tails of pre-mix ratio in grams of	sodium carbonate	Submitted		
3.2.P.2	Please provide Brand 1	name, Batch #, Manufacturer name performance of Pharmaceutica		Submitted		
3.2.P.8		nts for Procurement of API appro		Submitted		
	 Please submit COA of 	API used in manufacturing of sta		Submitted		
		arding 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						

• 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

Marketing Authorization Holder	M/s Misaq Pharmaceutical Pvt. Ltd. (DML # 000985) Plot No. 7-B, Woven Garments Zone, Value Addition Khurrianwala, Sahianwala Road, Faisalabad
	M/s Misaq Pharmaceutical Pvt. Ltd. (DML # 000985) Plot No. 7-B, Woven Garments Zone, Value Addition Khurrianwala, Sahianwala Road, Faisalabad
	 ✓ 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
	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)
	☑ Domestic sale☐ Export sale☐ Domestic and Export sales
Dy. No. and date of submission	Dy. No. ZSZ-TYW-N7VT Dated 17-04-2024
	PKR 30000/-: Dated 01-03-2024 Slip # 177082724679
The proposed proprietary name / brand name	Miodine 7.5% Solution
Active Pharmaceutical ingredient	Each 1ml Contains: - Povidone Iodine 75mg equivalent to Available Iodine
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
manufacturer.	M/s Caliber Chemicals Pvt. Ltd. Address: Plot No. 901/A, 901/B, 903, 905, 907, 1002, 1004, GIDC Sarigam, Tal, Umbergaon, Sarigam, Valsad, Gujrat Ind GMP Validity: 12-06-2025
	Firm has submitted QOS as per WHO QOS-PD template. F summarized information related to nomenclature, structure,

	Reference of previous appr tudy data of the firm (if any		oncations with	Stability Submitted		
1 1				ong WITH STABILITY	STUDY DATA	
No. of Batches				ONG WITH STADIL ITY	CONTINUE DATE A	
	Date of Initiation	31-0	08-2023	31-08-2023	31-08-2023	
	Manufacturing Date		3-2023	08-2023	08-2023	
		ttles (60ml)	100 Bottles (60ml)	100 Bottles (60ml)		
			PV1-001	TRS-PV1-002	TRS-PV1-003	
Frequency		Real Time	e: 0, 3, 6, 9, 12	ed: 0, 3, 6 (Months) e: 0, 3, 6, 9, 12 (Months)		
Time Peri	iod		e: 06 months red: 06 months			
Stability S	Storage Condition		: 30°C ± 2°C / 65% ± 5%RH ed: 40°C ± 2°C / 75% ± 5%RH			
_	on of Pack er closure system)		colored solution filled in 60ml pet bottle with cap.			
	API Lot No.	PVI-G-50		on, Sarigam, Valsad, Gujrat I	ingia.	
Manufact	urer of API	Address:	ber Chemicals Pvt. Ltd. Plot No. 901/A, 901/B, 903, 905, 907, 1002, 1004, & 1006, GIDC Tal, Umbergaon, Sarigam, Valsad, Gujrat India.			
_	1		ABILITY STU	61		
	Analytical validation/verification of p	method	Firm has submitted analytical method validation study reports for drug substance as well as drug product.			
	Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III (Drug Product): Pharmaceutical Equivalence and Comparative Dissolution Profile		Reference product: Pyidine 7.5% Manufactured by: Cortex Pharma Testing Parameters: USP Specifications			
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.			
			Climatic cond Real time stal	Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 36 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH		
			nomenclature manufacturer specifications and justificati	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.		
	I		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.			

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.	1
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.

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				
Pharmaco-therapeutic Group of (API)	Antiseptic, germicidal				
Pharmaceutical form of applied drug	Topical solution				

	Reference to Finished produspecifications	ıct	USP Specifications		
	Proposed Pack size		As per SRO		
	Proposed unit price		As per SRO		
	authorities For generic drugs (me-too status) Name and address of API manufacturer. Module-II (Quality Overall Summary) Module-III (Drug Substance): Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III (Drug Product):		MHRA approved formulation		
			Pyodine 10% Solution by Brookes Pharma		
			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		
			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.		
			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.		
			Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 36 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH		
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
	Pharmaceutical Equivaler Comparative Dissolution Pr		Reference product: Pyodine 10% Manufactured by: Broookes Pharma Testing Parameters: USP Specifications		
	Analytical method validation/verification of product		substance as well as drug product.		
			ABILITY STUDY DATA		
Manufact	Address:		Der Chemicals Pvt. Ltd. Plot No. 901/A, 901/B, 903, 905, 907, 1002, 1004, & 1006, GIDC Γal, Umbergaon, Sarigam, Valsad, Gujrat India.		
	API Lot No.	PVI-G-50	0		
	on of Pack r closure system)	Brownish	colored solution filled in 60ml pet bottle with cap.		
Stability S	Storage Condition		$30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ ed: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Peri	od	Real time	: 06 months		

	A	Accelerate	ed: 06 months			
Frequen	•		ed: 0, 3, 6 (Months) e: 0, 3, 6, 9, 12 (Months)			
	Batch No.	TRS-	-P10-001	TI	RS-P10-002	TRS-10-003
	Batch Size	100 Bo	ttles (60ml)	100	Bottles (60ml)	100 Bottles (60ml)
	Manufacturing Date	08	-2023		08-2023	08-2023
	Date of Initiation	31-0	08-2023	3	31-08-2023	31-08-2023
	No. of Batches				03	
	DOCUMENTS / DATA TO	O BE PR	OVIDED AL	ONG W	TH STABILITY	STUDY DATA
1.	Reference of previous approve study data of the firm (if any)	al of app	lications with	stability	Submitted	
2.	Approval of API/ DML/GMP issued by concerned regulatory				Submitted	
3.	Documents for the procureme DRAP (in case of import).	ent of Al	PI with appro	val from	Material loan from Quantity: 2 kg Dated: 10-08-202	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.					ted analytical record for
5.	Compliance Record of HPLC software 21CFR & audit trail Not required 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 d logger for temperature and humidimonitoring of real time and accelerate stability chambers.					
Remark	ks of Evaluator:					
	n: Approved.					
	ufacturer will place first three and on accelerated studies for s					
• Man	nut on accelerated studies for some stud		_			
			New Lice	nse		
	Licensing Board in its 286 th me to M/s Pharman Pharmaceutica					
611.	Name, address of Applicant Marketing Authorization H			59, Khat		l. (DML # 000958) Tehsil Wazirabad, Dist.
Name, address of Manufacturing site.				59, Khat		l. (DML # 000958) Tehsil Wazirabad, Dist.
	Status of the applicant		☑ Manufacturer☐ Importer☐ Is involved in none of the above (contract giver)			act giver)
	GMP status of the firm		New License	-		
	Evidence of approvamanufacturing facility	al of	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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 60 months Climatic conditions: $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \pm 5\%$ 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.			

	Comparative Dissolution Profile		Manufacture	ed by: GS	Zyrtec Oral Solution SK USP Specifications	
	Analytical validation/verification of	product	substance as v	Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
		STA	ABILITY STU	DY DAT	Γ A	
Manufa	cturer of API	eekara Organio Plot No. 159/A areddy Dist-502	, S.V. Co-	op. Ind. Estate, IDA angana, India	Bollaram, Jinnaram	
	API Lot No.	CTZ0872	1			
	tion of Pack ner closure system)	Colorless	and Banana fla	avor syruj	p filled in amber gla	ss bottle
Stability	y Storage Condition		: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ ed: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Time Pe	eriod		: 06 months ed: 06 months			
Frequen	ncy		ed: 0, 3, 6 (Mo e: 0, 3, 6, 9, 12)	
	Batch No.	CZ	Z22-01		CZ22-002	CZ22-03
	Batch Size	60	Litres		60 Litres	60 Litres
	Manufacturing Date	12	2-2022		12-2022	12-2022
	Date of Initiation	15-	12-2022	1	5-12-2022	15-12-2022
	No. of Batches				03	
	DOCUMENTS / DATA	A TO BE PR	ROVIDED AL	ONG W	ITH STABILITY S	TUDY DATA
1.	Reference of previous app study data of the firm (if an		olications with	stability	Submitted	
2.	Approval of API/ DML/Gissued by concerned regula				Submitted	
3.	Documents for the procur DRAP (in case of import).	ement of A	PI with approv	val from	Material loan from Quantity: 3 kg Dated: 29-04-2022	
4.	-	a of stability batches will be supported by attested respective uments like chromatograms, Raw data sheets, COA, mary data sheets etc.				
5.	Compliance Record of HPLC software 21CFR & audit trail Submitted eports on product testing					
6.	Record of Digital data lo monitoring of stability char	_	-	logger for tem	ed record of digital data perature and humidity al time and accelerated	
	ks of Evaluator:		4.			
3.2.S.7		data of APi a		ns of Zone	e IVA or Zone IV-B	Status 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. ☑ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)				
	Status of the applicant					
	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,				

cription, ufacture, alidation ications, s, batch haterials,			
afacture, alidation ications, s, batch naterials,			
afacture, alidation ications, s, batch naterials,			
for drug			
for drug			
İ			
TI Pharma Limited 3.5 KM, HEAD BALOKI ROAD, PHOOL NAGAR, KASUR PAKISTAN			
95 (Paracetamol micronized)			
uspension are packed in plastic bottle with plastic cap, further packed in along with patient leaflet insert			
2			
cord for			
2			

6.	Record of Digital data logger for tem monitoring of stability chambers (real tin	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.				
Remar	ks of Evaluator:		·			
Mar life aMar	and on accelerated studies for six montl	ns as per the commitmetion of first three batch	m stability studies throughout proposed shelf ent submitted in the registration application. hes as per the commitment submitted in the			
(DML)			proved the grant of Drug Manufacturing License ditional sections including Sterile Powder Vials			
613.	Name, address of Applicant / Marketing Authorization Holder		uticals Pvt. Ltd. (DML # 000772) SS-2, Industrial Zone Rawat Islamabad.			
	Name, address of Manufacturing site.		uticals Pvt. Ltd. (DML # 000772) 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					
	Status of application	☐ New Drug Product (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-ZZ	MB 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				
	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 form	ulation			
	For generic drugs (me-too status)	Oxidil by Sami Pharma				

	Name and address manufacturer.	of API				
	Summary) Module-III (Drug Substance): Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III (Drug Product):		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.			
			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.			
			Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 24 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH			
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.			
	Pharmaceutical Equivale Comparative Dissolution P		Reference product: Rocephin 1 gram injection Manufactured by: Martin Dow Testing Parameters: USP Specifications			
	Analytical validation/verification of property of the control of t		Firm has submitted analytical method validation study reports for drug substance as well as drug product.			
		STA	ABILITY STU	DY DATA		
Manufact	urer of API		nuhai United Laboratories Co. Limited No. 2428, Ajiroad Sanzao Town, Jinan District, Zhuhai Guangdong,			
	API Lot No.	30522060	125			
	on of Pack er closure system)	Colorless	and Banana flavor syrup filled in amber glass bottle			
		$20^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ $200^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$				
		: 06 months ed: 06 months				
1 •			ed: 0, 3, 6 (Months) e: 0, 3, 6, 9, 12 (Months)			
	Batch No.	TR-	INJ-001	TR-INJ-002	TR-INJ-003	
	Batch Size	500	0 Vials	500 Vials	500 Vials	
N	Manufacturing Date		2-2022	12-2022	12-2022	
Date of Initiation 26-1		12-2022	26-12-2022	26-12-2022		

	No. of Batches 03						
	DOCUMENTS / DATA TO B	BE PROVIDED ALONG W	TH STABILITY ST	TUDY DATA			
1.	Reference of previous approval of study data of the firm (if any)	Submitted					
2.	Approval of API/ DML/GMP cer issued by concerned regulatory aut		Submitted				
3.	Documents for the procurement DRAP (in case of import).	Material loan from F Quantity: 10 kg Dated: 23-11-2022	Hi-Medic Pharmaceuticals				
4.	Data of stability batches will be sup documents like chromatograms, summary data sheets etc.			d analytical record for			
5.	Compliance Record of HPLC so reports on product testing	ftware 21CFR & audit trail	Submitted				
6.	Record of Digital data logger fo monitoring of stability chambers (r	1	logger for temp	d record of digital data erature and humidity I time and accelerated			
Remarl	ks of Evaluator:						
Secction		Observations		Status			
3.2.S.7	•	•	e IVA or Zone IV-B	Submitted			
D	as per climatic conditions of P n: Approved.	akistan.					
regis	Licensing Board in its 270th meetin (DML) to M/s Metro Pharmaceuti (Cepalosporin) Section.	New Section g held on 23rd May 2019, app	proved the grant of Dr	ug Manufacturing License			
614.	Name, address of Applicant / Marketing Authorization Hold	M/s Metro Pharmace Plot no 14, street no S					
	Name, address of Manufacturing	site. M/s Metro Pharmace Plot no 14, street no S	,	,			
	Status of the applicant	☑ Manufacturer☐ Importer☐ Is involved in none	of the above (contract	t giver)			
	GMP status of the firm	New License					
	Evidence of approval of New License manufacturing facility						
	Status of application	(NDP) act (GDP)					
	Intended use of pharmaceu product	☐ Export sale					
	Dy. No. and date of submission	Dy. No. SMG-Y7V-Q7	Γ32 Dated 06-03-202	4			
	Details of fee submitted	PKR 30000/-: Dated 2: Slip # 01566705845	5-01-2024				

manufacturing process and 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,	The proposed proprietary name / brand name	Zigam 400 mg Capsule
Pharmaceutical form of applied drug Dral hard gelatin capsule	Active Pharmaceutical ingredient	
Reference to Finished product specifications Proposed Pack size Proposed and product size Proposed Pack size For generic drugs (me-too status) Name and address of API Manufacturer. Middule-II (Quality Overall Summary) Module-II (Quality Overall Summary) Module-III (Drug Substance): Module-III (Drug Substance): 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 specification, reference standard, container closure system and stability studies of drug substance and trug product. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturers, description of manufacturers, description of manufacturers, description of manufacturers, description of manufacturers, description of manufacturers, description of manufacturers, description of manufacturers, description of manufacturers, description of manufacturers and trug substance and stability studies of drug substance and stability studies of of months climatic conditions: 30°C ± 2°C / 75% ± 5% RH Module-III (Drug Product): Stability Studies of Drug Substance (Conditions & duration of Stability studies) Accelerated stability data for 36 months Climatic conditions: 30°C ± 2°C / 75% ± 5% RH Firm has submitted data of drug product, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Pharmaceutical Equivalence and 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.		Cephalosporins
Specifications Proposed Pack size 5s, 10s, & 100's	Pharmaceutical form of applied drug	Oral hard gelatin capsule
Proposed unit price	_	DRAP's Specifications
The status in reference regulatory authorities For generic drugs (me-too status) Name and address of API manufacturer. Name: CTI 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. 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 of specification, reference standard, container closure system and stability studies of drug substance. Stability Studies of Drug Substance (Conditions & duration of Stability studies of drug substance) 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 Firm has submitted data of drug product including its description, onemosition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Reference product: Cefiget Capsule 400 mg Manufactured by: Opal Laboratories Testing Parameters: DRAP's Specifications Comparative Dissolution Profile: similarity betcen reference and manufacturer's product.	Proposed Pack size	5s, 10s, & 100's
Rame and address of API manufacturer.	Proposed unit price	As per SRO
Name and address of API manufacturer. Name: CTI Pharma Limited Address: 3.5 KM, HEAD BALOKI ROAD, PHOOL NAGAR, KASUR PAKISTAN Module-II (Quality Summary) Module-III (Quality Overall 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. 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 of drug substance. Accelerated stability data for 36 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 Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of specifications, reference standard or materials, container closure system and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile: Analytical method validation study reports for drug vubstance as well as drug product.		MHRA approved formulation
Module-II (Quality Overall Summary)	For generic drugs (me-too status)	Cefiget by Opal
Summary) 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. 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 of drug substance. Stability Studies of Drug Substance (Conditions & duration of Stability studies of drug substance. 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 Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile: similarity beteen reference and manufactured by: Opal Laboratories Testing Parameters: DRAP's Specifications Comparative Dissolution Profile: similarity beteen reference and manufacturer's product.		Address: 3.5 KM, HEAD BALOKI ROAD, PHOOL NAGAR, KASUR
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. Accelerated stability data for 06 months (Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 36 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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. Firm has submitted analytical method validation study reports for drug substance as well as drug product.	` ` `	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
(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 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.	Module-III (Drug Substance):	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
composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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.	(Conditions & duration of Stability	Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 36 months
Comparative Dissolution Profile 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.	Module-III (Drug Product):	composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials,
validation/verification of product substance as well as drug product.	1	Manufactured by: Opal Laboratories Testing Parameters: DRAP's Specifications Comparative Dissolution Profile: similarity beteen reference and
	validation/verification of product	substance as well as drug product.

	1	Name: CITI Pharma Limi Address: 3.5 KM, HEAD		OAD, PHOOL NAGA	AR, KASUR PAKISTAN	
	API Lot No.	CFM2201015				
	Description of Pack (Container closure system) 1 x 5s capsules packed in ALU ALU blisters					
Stability S	\mathcal{C}	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$				
Time Peri		Real time: 06 months Accelerated: 06 months				
Frequency	•	Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6, 9, 12)		
	Batch No.	TBC- 001	,	TBC- 002	TBC- 003	
	Batch Size	1500 Capsules	15	00 Capsules	1500 Capsules	
N	Manufacturing Date	12-2022		12-2022	12-2022	
	Date of Initiation	27-12-2022	2	27-12-2022	27-12-2022	
	No. of Batches			03		
	DOCUMENTS / DATA T	O BE PROVIDED AL	ONG W	TH STABILITY	STUDY DATA	
	Reference of previous approverudy data of the firm (if any)	al of applications with	stability	Submitted		
	Approval of API/ DML/GMP ssued by concerned regulatory			Submitted		
	Documents for the procureme DRAP (in case of import).	ent of API with appro-	val from	Locally procured		
d	Data of stability batches will be documents like chromatogra summary data sheets etc.				tted analytical record for	
	Compliance Record of HPLC reports on product testing	software 21CFR & a	udit trail	Submitted		
	Record of Digital data logger monitoring of stability chamber			logger for ter	mperature and humidity real time and accelerated	
Remarks	of Evaluator:					
Decision:	: Approved as per the DRAP	specification vide lette	r No. F.	14-1/2022 dated 1	4 th March, 2022	
Manufac	Licensing Board in its 277 th eturing License (DML) to M/s Ointment/Gel (Steroid).		-16^{th}			
615.	Name, address of Applican Marketing Authorization H			atories Limited (D a, Khyber Pakhtu	· ·	
	Name, address of Manufactu		e. M/s Ferozsons Laboratories Limited (DML # 000038) Amangarh, Nowshera, Khyber Pakhtunkhwa.			
	Status of the applicant	☑ Manufactu☐ Importer☐ Is involved		of the above (contr	act giver)	
	GMP status of the firm	☐ Is involved in none of the above (contract giver) GMP Validity: 14-06-205			···· 6 -··-/	
			of New Section			

manufacturing facility	
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. 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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 60 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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,

			analysis, justi	fication o		nalytical procedures, batch erence standard or materials,
	Pharmaceutical Equiva Comparative Dissolution	Reference pr Manufacture Testing Para	ed by: GS			
	Analytical				•	dation study reports for drug
	validation/verification of	<u> </u>	substance as v		0.1	
Manuf	acturer of API	_	urisco Pharma			
Manui	acture of All		Badu Industria			Zhejiang Province 317200
	API Lot No.	AF-B-210)501 &			
	ption of Pack iner closure system)	Single 10	grams alumini	um collaj	psible tube is packe	d ina cardboard box.
Stabili	ty Storage Condition		: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ ed: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$			
Time F	Period		: 06 months ed: 06 months			
Freque	ency		ed: 0, 3, 6 (Mo e: 0, 3, 6, 9, 12		nths)	
	Batch No.	33	8NS12		338NS13 338NS14	
	Batch Size	350) grams		350 grams 350 grams	
	Manufacturing Date	06	5-2023		06-2023	06-2023
	Date of Initiation	24-0	06-2023	24-06-2023		24-06-2023
	No. of Batches				03	
	DOCUMENTS / DATA	TO BE PR	ROVIDED AL	ONG W	TH STABILITY	STUDY DATA
1.	Reference of previous approximately data of the firm (if any		olications with	stability	Submitted	
2.	Approval of API/ DML/GM issued by concerned regulat				Submitted	
3.	Documents for the procure DRAP (in case of import).	ement of A	PI with appro	val from	Quantity: 34 grar Dated : 23-08-202	
4.	Data of stability batches wil documents like chromato summary data sheets etc.	•	•		tted analytical record for	
5.	Compliance Record of HP reports on product testing	Compliance Record of HPLC software 2 reports on product testing			Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			logger for ter	ted record of digital data mperature and humidity eal time and accelerated	
Remar	ks 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 Oral Dry Powder for Suspension (Cephalosporin). i. ii. Capsule (Cephalosporin) Section Tablet (General) Section iii. Injection Ampoule (General) Section. iv. **616.** Name, address of Applicant / M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986) **Marketing Authorization Holder** 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 ☐ Importer ☐ Is involved in none of the above (contract giver) GMP status of the firm New License of New License Evidence of approval manufacturing facility 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. SEQ-WMX-99NQ Dated 22-04-2024 Details of fee submitted PKR 30000/-: Dated 18-04-2024 Slip # 8345618127 The proposed proprietary name / Muracef 125mg/5ml Dry Suspension brand name Strength / concentration of drug of Each 5 ml of reconstituted Suspension contains: -Active Pharmaceutical ingredient Cefadroxil Monohydrate equivalent to (API) per unit Cefadroxil 125 mg Pharmaco-therapeutic Group of Cephalosporin (API) Pharmaceutical form of applied drug Oral Powder for reconstitution Reference to Finished product **USP Specifications** specifications Proposed Pack size As per SRO Proposed unit price As per SRO The status in reference regulatory Biodroxil 125mg/5ml by Sandoz GMBH, Austria Listed in European authorities Medicine Agency (EMA) For generic drugs (me-too status) Sephidrox by Seraph Pharma Name and address of API Name: M/S Pharmagen Limited manufacturer. Address: 34-Km, Ferozepur Road, Lahore, Pakistan. **GMP Validity: compliant** Overall Firm has submitted QOS as per WHO QOS-PD template. Firm has Module-II (Quality Summary) summarized information related to nomenclature, structure, general

		manufacturing procedures a specification,	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):		nomenclature manufacturers specifications and justificati	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 St (Conditions & duration of studies)		Climatic cond Real time stat	tability data for (litions: $40^{\circ}\text{C} \pm 2^{\circ}$) bility data for 36 litions: $30^{\circ}\text{C} \pm 2^{\circ}$	$^{\circ}$ C / 75% \pm 5 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 Equivale Comparative Dissolution P		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 validation/verification of properties of the control of	method oduct	Firm has submitted analytical method validation study reports for drug substance as well as drug product.			
		STA	TABILITY STUDY DATA			
Manufact	urer of API		/S Pharmagen 34-Km, Feroze	Limited our Road, Lahore	e, Pakistan.	
	API Lot No.	002240/23	3-09/014			
	on of Pack r closure system)	White col	ored powder fi	lledin Glass Bott	le Dry Susp	ensions
	Storage Condition		: 30°C ± 2°C / 6 ed: 40°C ± 2°C	55% ± 5%RH / 75% ± 5%RH		
Time Peri	od	Real time	l time: 06 months elerated: 06 months			
Frequency	y	Accelerate	ed: 0, 3, 6 (Mo	,		
	Batch No.			T002		T003
	Batch Size		Bottles	600 Bott		600 Bottles
N	Manufacturing Date	11	-2023	11-202	23	11-2023
	Date of Initiation	08-1	11-2023	08-11-20)23	08-11-2023
	No. of Batches			03	3	
	DOCUMENTS / DATA	TO BE PR	ROVIDED AL	ONG WITH ST	ABILITY S	STUDY DATA
	Reference of previous approtudy data of the firm (if any)		olications with	stability Submi	tted	

Section	n Observations	
	ks of Evaluator:	
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.
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	· · · · · · · · · · · · · · · · · · ·
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally procured
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted

Section	Observations
3.2.P.8	Please submit the stability data for the 06 th 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.

	gistration 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				
		\square 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)				
	7-	☐ Generic Drug Product (GDP)				
	Intended use of pharmaceutical product	☑ Domestic sale				
	product	☐ 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				
	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 regrauthorities	ılatory	MHRA approved formulation				
For generic drugs (me-too	status)	Sephidrox by Seraph Pharma				
Name and address manufacturer.	of API	Name: M/S Pharmagen Limited Address: 34-Km, Ferozepur Road, Lahore, Pakistan. GMP Validity: compliant				
Module-II (Quality Summary)	Overall	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	ee):	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 S (Conditions & duration of studies)		Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 36 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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 Equivale Comparative Dissolution P		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 validation/verification of p	method roduct	Firm has submitted analytical method validation study reports for drug substance as well as drug product.				
		ABILITY STUDY DATA				
Manufacturer of API		/S Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan.				
API Lot No.	002240/23	3-09/014				
Description of Pack (Container closure system)	White col	ored powder filledin Glass Bottle Dry Suspensions				
Stability Storage Condition		: 30°C ± 2°C / 65% ± 5%RH ed: 40°C ± 2°C / 75% ± 5%RH				
		: 06 months ed: 06 months				

1 -		elerated: 0, 3, 6 (Mo Time: 0, 3, 6, 9, 12	•			
	Batch No.	T001	T002	T003		
	Batch Size	600 Bottles	600 Bottles	600 Bottles		
N	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 B	E PROVIDED AL	ONG WITH STABILIT	Y STUDY DATA		
	Reference of previous approval or tudy data of the firm (if any)	f applications with	stability Submitted			
	Approval of API/ DML/GMP cert ssued by concerned regulatory auth					
Ι	Documents for the procurement of DRAP (in case of import).					
d	Data of stability batches will be sup locuments like chromatograms, ummary data sheets etc.			mitted analytical record for		
	Compliance Record of HPLC sof eports on product testing	tware 21CFR & a	udit trail Submitted			
	Record of Digital data logger for nonitoring of stability chambers (re	•	ated) logger for t	nitted record of digital data emperature and humidity real time and accelerated ers.		
Remarks	of Evaluator:		•			
Section 3.2.P.8	Please submit the stability data f	Observa Octh		11/2		
Manu life anManu	Approved. The registration letter facturer will place first three produced on accelerated studies for six national perform process varation application.	duction batches on nonths as per the c	long term stability studion ommitment submitted in	es throughout proposed shelf the registration application.		
618.	Name, address of Applicant / Marketing Authorization Hold		M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986) Plot No. 95-A, , Industrial Estate KLP Road, Rahim Yar Khan.			
	Name, address of Manufacturing		Pharmaceuticals (SMC-P A, , Industrial Estate KLl	vt) Ltd (DML # 000986) P Road, Rahim Yar Khan.		
	Status of the applicant	☐ Importer	 ☑ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver) 			
	GMP status of the firm	New License	New License			
	Evidence of approval manufacturing facility	of New License	New License			
	Status of application	_	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)			
	Intended use of pharmaceu product	tical ⊠ Domestic s □ Export sale □ Domestic a	sale e and Export sales	0004		
	Dy. No. and date of submission	Dy. No. Z98-	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
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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 36 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ 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 validation/verification of p		Firm has subr		•	dation study reports for drug		
	STABILITY STUDY DATA							
Manufa	Manufacturer of API Name: Name: Naddress				, Lahore, Pakistan.			
	API Lot No.	00510931	/468/2023					
	tion of Pack ner closure system)	Alu-Alu t	olisters in bleac	h card un	nit carton along with	h leaflet		
Stability	y Storage Condition		: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ ed: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$					
Time Po	eriod		: 06 months ed: 06 months					
Frequer	ncy		ed: 0, 3, 6 (Mo e: 0, 3, 6, 9, 12		nths)			
	Batch No.	ŗ	Γ001		T002	T003		
	Batch Size	1500) capsule	1:	500 capsule	1500 capsule		
	Manufacturing Date	11	1-2023		11-2023	11-2023		
	Date of Initiation	09-	11-2023	C	09-11-2023	09-11-2023		
	No. of Batches				03			
	DOCUMENTS / DATA	TO BE PE	ROVIDED AL	ONG W	ITH STABILITY	STUDY DATA		
1.	Reference of previous appr study data of the firm (if any		olications with	stability	Submitted			
2.	Approval of API/ DML/GM issued by concerned regulate				Submitted			
3.	Documents for the procure DRAP (in case of import).	ment of A	PI with appro	val from	Locally procured			
4.	Data of stability batches will documents like chromatog summary data sheets etc.					tted analytical record for		
5.	Compliance Record of HPI reports on product testing	LC software	e 21CFR & a	udit trail	Submitted			
6.	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.							
	ks of Evaluator:							
Sectio 3.2.P.3	Section Observations 3.2.P.8 Please submit the stability data for the last interval (06 th month) for both accelerated and real time conditions.							
	n: Approved. The registration							

- 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.	, <u></u>	M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd (DML # 000986) Plot No. 95-A, , Industrial Estate KLP Road, Rahim Yar Khan.
		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
	\square 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	
product	☐ 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
Details of fee sublifficed	Slip # 208287200
The proposed proprietary name / brand name	AQUA-NM Injection
Strength / concentration of drug of	Each glass ampoule contains: -
Active Pharmaceutical ingredient (API) per unit	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 <i>(self manufacturing)</i>
Module-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	Module-III (Drug Product):		Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
Pharmaceutical Equival Comparative Dissolution I		Reference pro Manufacture Testing Para	d by: GS		
Analytical validation/verification of p	method product	Firm has subm substance as v			dation study reports for drug
	STA	ABILITY STU	DY DAT	TA	
Manufacturer of API	Self-Manu	ufacturing			
API Lot No.	Not requi	red			
Description of Pack (Container closure system)	Clear colo	orless & odorles	ss liquid 1	filled in clear glass	ampoules.
Stability Storage Condition		: 30°C ± 2°C / 65% ± 5%RH ed: 40°C ± 2°C / 75% ± 5%RH			
Time Period		e: 06 months ted: 06 months			
Frequency		ed: 0, 3, 6 (Months) e: 0, 3, 6, 9, 12, 24 (Months)			
Batch No.	W	/N001		WN002	WN003
Batch Size	500 A	Ampoules	50	0 Ampoules	500 Ampoules
Manufacturing Date	10)-2023		10-2023	10-2023
Date of Initiation 02		10-2023	0	02-10-2023 02-10-2023	
No. of Batches				03	
DOCUMENTS / DATA	TO BE PE	ROVIDED ALC	ONG WI	TH STABILITY	STUDY DATA
	Reference of previous approval of applications with stability Submitted 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.			g	
3. Documents for the procure DRAP (in case of import).	Documents for the procurement of API with approval from Self-manufacturing			g	
documents like chromatog summary data sheets etc.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, product testing.			tted analytical record for	
5. Compliance Record of HPI reports on product testing	Compliance Record of HPLC software 21CFR & audit tra- reports on product testing		ıdit trail	Not required	
	Record of Digital data logger for temperature monitoring of stability chambers (real time and			Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated	
1				monitoring of r	real time and accelerated

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.

	nufacturer will perform process validation of first three batches as per the commitment submitted in the distration 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		
	GMP status of the firm	☐ Is involved in none of the above (contract giver) New License	
		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,	

			specifications and justification	, analytica on of spec	al procedures and i	aring process and controls, its validation, batch analysis e standard, container closure ance.
	(Conditions & duration of Stability studies)		Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 36 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH			
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 validation/verification of programmer values are seen as a second control of the cont		Firm has subn substance as v		•	dation study reports for drug
		STA	BILITY STU	DY DATA	Ā	
Manufacturer of API Name: M/S			S Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan.			
	API Lot No.	002230/23	3-09/014			
		or Round unco card unit carto			-alu blister. Blisters are	
Stability Storage Condition Real time:		: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ ed: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$				
Time Po	eriod		: 06 months ed: 06 months			
		ed: 0, 3, 6 (Months) :: 0, 3, 6, 9, 12, 24 (Months)				
	Batch No.	-	Γ001	T002		T003
	Batch Size	150	0 tablets	15	600 tablets	1500 tablets
	Manufacturing Date	10	0-2023]	10-2023	10-2023
	Date of Initiation	02-1	10-2023	02-10-2023		02-10-2023
	No. of Batches		03			
	DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				STUDY DATA	
1.	Reference of previous approstudy data of the firm (if any)	olications with	stability	Submitted		
2.	Approval of API/ DML/GM issued by concerned regulator			Submitted		
3.	Documents for the procurement of API with approval from Locally procured DRAP (in case of import).					
4.	Data of stability batches will documents like chromatogrammary data sheets etc.				tted analytical record for	

	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.		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:

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.

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Status of the applicant	☐ Manufacturer
	\square 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	☑ Finished Pharmaceutical product import
these	☐ 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/-: 23 rd June 2023
	Slip # 731600620
The proposed proprietary name / brand name	Norevell (Sevoflurane 100%) Inhalation Vapour, Liquid 250 ml
Strength / concentration of drug of Active	Each 250ml amber glass bottle contains
Pharmaceutical ingredient (API) per unit	Sevoflurane100% (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°C ±2°C Relative Humidity: 75% ± 5%. Long term Storage Conditions: Duration: 36 months Temperature: 30°C ±2°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

	The submit of grant regulated correct 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)	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, 4 th 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/-: 26 th 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: Iohexol755mg/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 $40^{\circ} \pm 2^{\circ} \text{ C}/75 \pm 5\% \text{ RH for } 06 \text{ months.}$ Real time: $25^{\circ} \pm 2^{\circ} \text{ C}/60 \pm 5\% \text{ RH for } 36 \text{ months.}$
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 TM (other name ACCUPAQUE TM) 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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Relative Humidity: $75\% \pm 5\%$.
	Long term Storage Conditions: Duration: 36 months Temperature: 25°C ±2°C 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	Submitted
	format with pack sizes/volume per pack.	
ii.	The stability data submitted for ZONE IV-A,	The stability studies data for 12 months is attached.
	is for 09 months while the claimed shelf life is	Firm requested to kindly grant us shelf life for 2 years
	of 2 years. You are required to submit complete	(24 months)
	stability data as per claimed shelf life.	
iii.	Submit hard copy of original Legalized or	The hard copies of apostilled CoPP, GMP, and letter of
	apostille CoPP/ FSC and GMP and original	authorization is being submitted to DRAP office of reg
	Letter of authorization in office of Reg-Import	Imp and vet section of PE&R division.
	& 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: 28 th 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/-: 26 th 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: Iohexol755mg/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	-
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 40° ±2 ° C/75 ± 5% RH for 06 months. Real time: 25° ±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 and Comparative Dissolution Profile	Name: OMNIPAQUE TM (other name ACCUPAQUE TM) 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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Relative Humidity: $75\% \pm 5\%$.
	Long term Storage Conditions: Duration: 09 months Temperature: 30°C ±2°C 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	Submitted
	format with pack sizes/volume per pack.	
ii.	The stability data submitted is for 09 months	The stability studies data for 12 months is attached.
	while the claimed shelf life is of 2 years. You	Firm requested to kindly grant us shelf life for 2 years
	are required to submit complete stability data	(24 months)
	as per claimed shelf life.	
iii.	Submit hard copy of original Legalized or	The hard copies of apostilled CoPP, GMP, and letter of
	apostille CoPP/ FSC and GMP and original	authorization is being submitted to DRAP office of reg
	Letter of authorization in office of Reg-Import	Imp and vet section of PE&R division.
	& 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)	Original & Legalized Date of Legalization: 28 th 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	☑ Finished Pharmaceutical product import
these	☐ 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/-: 26 th 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	Each 200 ml vial contains:
Pharmaceutical ingredient (API) per unit	Iohexol755mg/ml (755mg Iohexol equivalent to 350mg I)
Dhawsaaasti aal fawa of analiad dusa	
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 $40^{\circ} \pm 2^{\circ} \text{ C}/75 \pm 5\% \text{ RH for } 06 \text{ months.}$ Real time: $25^{\circ} \pm 2^{\circ} \text{ C}/60 \pm 5\% \text{ RH for } 36 \text{ months.}$
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 TM (other name ACCUPAQUE TM) 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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Relative Humidity: $75\% \pm 5\%$. Long term Storage Conditions: Duration: 09 months Temperature: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Relative Humidity: $75\% \pm 5\%$.
	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	Submitted
	format with pack sizes/volume per pack.	
ii.	The stability data submitted is for 09 months	The stability studies data for 12 months is attached.
	while the claimed shelf life is of 2 years. You	Firm requested to grant shelf life for 2 years (24)
	are required to submit complete stability data	months)
	as per claimed shelf life.	
iii.	Submit hard copy of original Legalized or	The hard copies of apostilled CoPP, GMP, and letter of
	apostille CoPP/ FSC and GMP and original	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:

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 232 nd meeting held on 29 th & 30 th 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: Iohexol755mg/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

	Reference of previous appr tudy data of the firm (if any		oncations with	stability Submitted		
1 1				ong WITH STABILITY	STUDY DATA	
	No. of Batches	TO DE DE	OTHER 15	03	CONTINUE A STA	
	Date of Initiation	28-0	09-2023	28-09-2023	28-09-2023	
<u> </u>		0 -2023	09 -2023	09 -2023		
			0 vials	100 vials	100 vials	
		3- 278/T1/S1	RD/PR23- 278/T1/S2	RD/PR23- 278/T1/S3		
Frequency	requency Accelerated: Real Time: 0			(Months)		
Time Peri	iod	Real time: 06 months Accelerated: 06 months				
Stability S	Stability Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$					
•	Description of Pack (Container closure system) A clear glass vial containing with a blue color flip off seal		•	n free from foreign particles,		
	API Lot No.	Zhejiang, C0042308				
Manufacturer of API Name: Zh Address:		ejiang Hichi Pharmaceutical Corporation Limited Changshun Road, Bingang Industrial Zone, Shamen Town, Yuhuan,				
•			ABILITY STU			
	Analytical validation/verification of p	method	Firm has submitted analytical method validation study reports for drug substance as well as drug product.			
	Module-III (Drug Product): Pharmaceutical Equivalence and Comparative Dissolution Profile		Reference product: Omnipaque 50ml Manufactured by: GE HealthCare Ireland. Testing Parameters: USP Specifications			
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.			
	Stability Studies of Drug S (Conditions & duration of studies)		Climatic cond Real time stat	Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 24 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH		
			nomenclature manufacturers specifications and justificati	, structure, general properties, description of manufactor, analytical procedures and	substance data related to es, solubility, physical form, uring process and controls, its validation, batch analysis e standard, container closure ance.	
			manufacturing procedures a specification,	g process and controls, nd its validation, batch and	anufacturers, description of specifications, analytical nalysis and justification of ainer closure system and ig product.	

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.	I
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.

Section	Observations	Status
1.3.4	• Please submit GMP certificate of your firm which should be valid till date.	Submitted
	• Please justify that why analytical testing of free iodine has not been made part of your stability study?	Results are now submitted.
3.2.P.8	• 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 (06 th month).	Submitted

- 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 05 th August 2021.
	Evidence of approval of manufacturing facility	Central Licensing Board in its 232 nd meeting held on 29 th & 30 th 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	Each 100 ml vial contains: Iohexol755mg/ml
(API) per unit	(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 AP manufacturer.	Name: Zhejiang Hichi Pharmaceutical Corporation Limited Address: Changshun Road, Bingang Industrial Zone, Shamen To Yuhuan, Zhejiang, China. GMP validity: 13-01-2024
Module-II (Quality Overal Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm summarized information related to nomenclature, structure, ger properties, solubility, physical form, manufacturers, description manufacturing process and controls, specifications, analy procedures and its validation, batch analysis and justification specification, reference standard, container closure system stability studies of drug substance and drug product.
Module-III (Drug Substance):	Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubility, physical f manufacturers, description of manufacturing process and contapecifications, analytical procedures and its validation, batch and and justification of specification, reference standard, container classystem and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Accelerated stability data for 06 months Climatic conditions: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH. Real time stability data for 24 months Climatic conditions: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH
Module-III (Drug Product):	Firm has submitted data of drug product including its descrip composition, pharmaceutical development, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specificationallytical procedures, validation of analytical procedures, by analysis, justification of specifications, reference standard or materic 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	Firm has submitted analytical method validation study reports for substance as well as drug product.
validation/verification of product	0.1

		Address: Changshun Road, Bing Zhejiang, China.		ang Industrial Zor	ne, Shamen Town, Yuhuan,	
	API Lot No.	C0042308001				
	ption of Pack iner closure system)	A clear glass vial contain with a blue color flip off		ar, colorless solution	n free from foreign particles,	
Stabilit	ty Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$				
Time P	Period	Real time: 06 months Accelerated: 06 months				
Freque	ncy	Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6, 9, 12	,)		
	Batch No.	RD/PR23- 271/T1/S1	RD/Pl	R23- 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 W			TH STABILITY	STUDY DATA		
1. Reference of previous approval of applications with stability study data of the firm (if any)			stability	Submitted		
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			Submitted		
3.				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.					tted analytical record for	
5.	5. Compliance Record of HPLC software 21CFR & audit trainereports on product testing			Submitted		
6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)				logger for ter	ted record of digital data mperature and humidity real time and accelerated s.	

Section	Observations	Status
1.3.4	• Please submit GMP certificate of your firm which should be valid till date.	Submitted
	• Please justify that why analytical testing of free iodine has not been made part of your stability study?	Results are now submitted.
3.2.P.8	• 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 (06 th month).	Submitted

- 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.

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 $40 \pm 5^{\circ}\text{C}$ / RH 75% for 06 months. Real time: $30 \pm 5^{\circ}\text{C}$ / 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.

28. Name, addres	s of Applicant / Importer	M/s Ghazali Brothers Address: : 1st Floor, Azzainab Court, Campbell Street, Karachi Pakistan				
Details of Drug	g 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 authorization h	address of marketing 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 expor	ting country	CHINA.				

Date of Legalization: not provided CoPP: Firm has submitted CoPP certificate (N 20230601002) dated 01-06-2023 issued by Anhui Dru Administration China. The CoPP specifies free sale status of the product in count of export along with its availability. CoPP Validity: 31-05-2028 GMP: The firm has also submitted GMP compliant certificate No.: 20170363, Valid till invalidation of drumanufacturing license i.e. 31-12-2025 Details of letter of authorization / sole agency agreement Firm has submitted letter of authorization from Anhui Ocea Pharmaceutical Co., Ltd. Address: No.1918, Longhua Roa Bengbu, Anhui Province, China. The letter certifies that "M/s Ghazali Brothers, 1st Floo Azzainab Court, Campbell Street, Karachi Pakistan" is the exclusive agent to promote, register, commercialize and distribut company's (Calcium Gluconate Injection 1g/10ml) product in the	T	<u> </u>
CoPP: Firm has submitted CoPP certificate (N 20230611002) dated 01-06-2023 issued by Anhui Dra Administration China. The CoPP specifies free sale status of the product in count of export along with its availability. CoPP Validity: 31-05-2028 GMP: The firm has also submitted GMP compliancertificate No.: 20170363, Valid till invalidation of dramanufacturing license i.e. 31-12-2025 Firm has submitted letter of authorization from Anhui Ocer agency agreement Sole agency agreeme	Detail of certificates attached (CoPP, Free	
Details of letter of authorization / sole agency agreement Details of letter of authorization / sole agency agreement Sternight / Sole agency agreement Status of the applicant Status of the applicant Status of application Details of application Status of application Status of application Details of pharmaceutical Products, specify one the these For imported products, specify one the specified by the sole application Dy. No. and date of submission Dy. No. Tu3-9GJ-PAD7 Dated: 08-03-2024 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 Strength / concentration of drug of Active Pharmaceutical form of applied drug Pharmaceutical form of applied drug Pharmaceutical form of applied drug Sterile Liquid for injection Pharmaceutical form of applied drug Sterile Liquid for injection Pharmaceutical form of applied drug Pharmaceutical form of paplied drug Sterile Liquid for injection Pharmaceutical form of paplied drug Pharmaceutical form of paplied drug Sterile Liquid for injection Pharmaceutical form of paplied drug Sterile Liquid for injection Pharmaceutical form of applied drug Sterile Liquid for injection Pharmaceutical form of applied drug Sterile Liquid for injection Pharmaceutical form of applied drug Sterile Liquid for injection Pharmaceutical form of applied drug Sterile Liquid for injection Pharmaceutical form of applied drug Sterile Liquid for injection Pharmaceutical form of applied drug Sterile Liquid for injection Pharmaceutical form of applied drug Sterile Liquid for injection P	sale certificate, Givir certificate)	 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
agency agreement Bengbu, Anhui Province, China. The letter certifies that "Ms Ghazali Brothers, 1st Floo Azainab Court, Campbell Street, Karachi Pakistan" is the exclusive agent to promote, register, commercialize and distribut company's (Calcium Gluconate Injection 1g/Ioml) product in the territory of Pakistan. The letter was issued on 28-07-2021 valid for 05 years. Status of the applicant □ Msunfacturer □ Is involved in none of the above (contract giver) Status of application □ New Drug Product (NDP) □ Seneric Drug Product (NDP		
Status of application Status of application Status of application Status of application Status of application Status of application Status of application Status of application Status of application Status of application Status of application Status of application Status of application Status of application Status of application Strength / concentration of drug of Activite Pharmaceutical ingredient (API) per unit Strength / concentration of frug of Activite Pharmaceutical form of applied drug Strengeth of Status of Finished Product Sterile Liquid for injection Pharmaceutical form of applied drug Pharmaceutical form of applied drug Sterile Liquid for injection Pharmacotherapeutic Group of (API) Sterile Liquid for injection Strenged Proposed Proposed Proposed Proposed Unit price Stap SRO Status in reference regulatory authorities Status in reference regulatory authorities Status in reference regulatory authorities Status in reference regulatory authorities		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
Status of application 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 □ Domestic and Export sales □ Domestic sale □ Export sale □ Domestic and Export sales □ Dome	Status of the applicant	☐ Manufacturer
Status of application		⊠ Importer
Intended use of pharmaceutical product Intended use of pharmaceutical product Intended use of pharmaceutical product Intended use of pharmaceutical product Intended use of pharmaceutical product Intended use of pharmaceutical product Intended use of pharmaceutical product import Intended use of pharmaceutical products, specify one the planta intended important and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of product import and local repackaging Intended use of product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of pharmaceutical product import and local repackaging Intended use of packaging Intended use of product import and local		☐ Is involved in none of the above (contract giver)
□ Export sale □ Domestic and Export sales	Status of application	
For imported products, specify one the these Bubmitted Buk import and local repackaging Buk import and local repackaging 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). **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 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 Proposed Pack size Glass Ampoule Proposed unit price As per SRO The status in reference regulatory authorities The status in reference regulatory authorities The status in reference regulatory authorities	Intended use of pharmaceutical product	☐ Export sale
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 Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Pharmaceutical form of applied drug Pharmacotherapeutic Group of (API) Reference to Finished product specifications Proposed Pack size Glass Ampoule Proposed unit price As per SRO The status in reference regulatory authorities		☐ Buk import and local repackaging
PKR 150000 dated 28-12-2023 (Slip # 67337134054). + PKR 150000 dated 01-03-2024 (Slip # 67337134054) The proposed proprietary name / brand name Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Pharmaceutical form of applied drug Sterile Liquid for injection Pharmacotherapeutic Group of (API) Reference to Finished product specifications Proposed Pack size Glass Ampoule Proposed unit price As per SRO The status in reference regulatory authorities	Dy. No. and date of submission	Dy. No. 7U3-9GJ-PAD7 Dated: 08-03-2024
The proposed proprietary name / brand name Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Pharmaceutical form of applied drug Pharmacotherapeutic Group of (API) Reference to Finished product specifications Proposed Pack size Glass Ampoule Proposed unit price As per SRO The status in reference regulatory authorities Calcium Gluconate Injection 1g/10ml Each 10 ml contains Calcium Gluconate 1 G Sterile Liquid for injection Used in treatment of calcium deficiency BP Specification Glass Ampoule USFDA & MHRA approved formulation	Details of fee submitted	
name Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Pharmaceutical form of applied drug Sterile Liquid for injection Pharmacotherapeutic Group of (API) Reference to Finished product specifications Proposed Pack size Glass Ampoule Proposed unit price As per SRO The status in reference regulatory authorities Each 10 ml contains Calcium Gluconate		PKR 150000 dated 01-03-2024 (Slip # 67337134054)
Pharmaceutical ingredient (API) per unit Pharmaceutical form of applied drug Sterile Liquid for injection Pharmacotherapeutic Group of (API) Reference to Finished product specifications Proposed Pack size Glass Ampoule Proposed unit price As per SRO The status in reference regulatory authorities Calcium Gluconate 1 G Sterile Liquid for injection BP Specification Glass Ampoule BP Specification USFDA & MHRA approved formulation		Calcium Gluconate Injection 1g/10ml
Pharmacotherapeutic Group of (API) Reference to Finished product specifications Proposed Pack size Glass Ampoule Proposed unit price As per SRO The status in reference regulatory authorities Used in treatment of calcium deficiency BP Specification Glass Ampoule USFDA & MHRA approved formulation	S S	
Reference to Finished product specifications Proposed Pack size Glass Ampoule Proposed unit price As per SRO The status in reference regulatory authorities USFDA & MHRA approved formulation	Pharmaceutical form of applied drug	Sterile Liquid for injection
Proposed Pack size Glass Ampoule Proposed unit price As per SRO The status in reference regulatory authorities USFDA & MHRA approved formulation	Pharmacotherapeutic Group of (API)	Used in treatment of calcium deficiency
Proposed unit price As per SRO The status in reference regulatory authorities USFDA & MHRA approved formulation	1	BP Specification
The status in reference regulatory authorities USFDA & MHRA approved formulation	Proposed Pack size	Glass Ampoule
The status in reference regulatory authorities USFDA & MHRA approved formulation	Proposed unit price	As per SRO
For generic drugs (me-too status) Locally registered	The status in reference regulatory	
	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 $40 \pm 5^{\circ}\text{C}$ / RH 75% for 06 months. Real time: $25 \pm 5^{\circ}\text{C}$ / 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: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Relative Humidity: $75\% \pm 5\%$.
	Long term Storage Conditions: Duration: 36 months Temperature: 30°C ±2°C 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 Roa 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			Pyodine 10% Solution of M/s Brookes Pharma (Reg. 009528)			
Name and address of API	Module-II (Quality Overall Summary)		M/s Prachi Pharmaceuticals Pvt. Ltd. E-108, MIDC Tarapur, Boisar-401506 Dist. Thane Maharashtra, India			
Module-II (Quality Overal			Firm has submitted QOS as per WHO QOS-PD templar. Firm has summarized information related to nomenclature structure, general properties, solubility, physical formanufacturer, description of manufacturing process a controls, specifications, analytical procedures and validation, batch analysis and justification of specification reference standard, container closure system and stabilistic studies of drug substance and drug product.			
Module-III Drug Substanc	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 $40^{\circ}C \pm 2^{\circ}C$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}C \pm 2^{\circ}C$ / $65\% \pm 5\%$ RH for 36 months.			
Module-III Drug Product:	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 Equivalent	ce	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 of product	ation/verification		Firm has submitted analytical method validation study reports for drug substance as well as drug product.			
	STABILIT	ΓY S'	ΓUDY DATA			
Manufacturer of API	M/s Prachi Phar Dist. Thane Mal	rmaceuticals Pvt. Ltd. E-108, MIDC Tarapur, Boisar-401506 harashtra, India				
API Lot Number	PD 222311504					
Description of Pack (Container closure system)	Brownis colored	d solution filled in 60ml pet bottle with cap.				
, .		$2 \pm 2^{\circ}C / 65\% \pm 5\% RH$ $C \pm 2^{\circ}C / 75\% \pm 5\% RH$				
Time Period Real time: 6 mo Accelerated: 6 r						
Frequency	Accelerated: 0, 3, Real Time: 0, 3,					
Batch No.	PV1		PV2	PV3		
Batch Size	100Bottles		100Bottles	100Bottles		

Manuf	acturing Date	09-2022		09-2022	09-2022	
No. of Batches						
	DOCUMENTS / DATA T	O BE PROVIDE	D AL	ONG WITH STABIL	ITY 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.			od & Drug Administration.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).			AD(PE&R)/PEC for e as Loan from M/s Pi invoice of M/s Pharm	copy of letter address to vidence of Borrowing of API harma wise lab Lahore. The a wise lab Lahore for povine by AD (I&E) DRAP, Lahore.	
4.	Data of stability batches attested respective docume Raw data sheets, COA, sun	nts like chromatog	grams,	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing				graph method of assay is	
6.					cord of digital data logger for dity monitoring of real time ty chambers.	
	rks of evaluator:					
	certificate of DS is not valid.	gubmit valid DN	MT /C!	MD contificate of Dwg	a Cubatanaa manufaatuuan	
	issuance of registration let		VIL/GI	vir certificate of Dru	g Substance manufacturer,	
630.	Name, address of Applican Authorization Holder		M/s Balance	ritish Pharmaceuticals,	23 Km Sheikhupura Road,	
	Name, address of Manufact	-	M/s Balahore	ritish Pharmaceuticals,	23 Km Sheikhupura Road,	
	Status of the applicant	٥	⊠ Man	ufacturer		
	GMP status of the firm		Addition or a contract of the	onal sections gran ations dated 27-12-2021	-	
	Evidence of approval of ma		Centra		approval granted by DRAP e letter No. F. 1-22/2010-Lic,	
	Status of application		⊠ Gen	Generic Drug Product (GDP)		
	Intended use of pharmaceu	tical product	⊠ Don	nestic and Export sales		
	Dy. No. and date of submis	sion I	Dy.No	18080 dated 18-07-202	3	
	Details of fee submitted		Rs. 30,000/- dated 02-06-2023 Slip No. 187032431745			
	The proposed proprietary name	ame / brand	Povdine 7.5% Solution			
	Strength / concentration of Pharmaceutical ingredient ((API) per unit F				
	Pharmacotherapeutic Group					

	Pharmaceutical form of app	plied drug	Topically liquid solution		
	Reference to Finished prod specifications	luct	USP specifications		
	Proposed Pack size		1's (60ml, 90ml,100ml, 450ml) Bottle		
	Proposed unit price		As per SRO		
	The status in reference regrauthorities	ulatory	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 i	nanufacturer.	M/s Prachi Pharmaceuticals Pvt. Ltd. E-108, MIDC Tarapur, Boisar-401506 Dist. Thane Maharashtra, India		
	Module-III (Quality Overall Summary) Module-III Drug Substance: Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Pharmaceutical Equivalence Analytical method validation/verification of product		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.		
			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		
			Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$. 75% \pm 5% RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / 65% \pm 5% RH for 36 months.		
			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.		
			Firm has submitted Pharmaceutical Equivalence of their product against the product Wondseptic 7.5% (Batch No. 2GLC1) manufactured by M/s Brooks Pharma.		
			Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
STABILIT		STABILIT	TY STUDY DATA		
Manufacturer of API M/s Prachi Phar Dist. Thane Mah			maceuticals Pvt. Ltd. E-108, MIDC Tarapur, Boisar-401506 harashtra, India		
API Lot	API Lot Number PD 222311504				
Description of Pack (Container closure system) Brownis colored		Brownis colored	d solution filled in 60ml pet bottle with cap.		
, , ,			$\pm 2^{\circ}$ C / 65% ± 5 %RH $^{\circ}$ C $\pm 2^{\circ}$ C / 75% ± 5 %RH		

Time I	Period	Real time: 6 month Accelerated: 6 mor					
Freque	Frequency Accelerated: 0, 3 Real Time: 0, 3,						
Batch	No.	PV1		PV2	PV3		
Batch	Size	100Bottles (60ml))	100Bottles (60ml)	100Bottles (60ml)		
Manuf	facturing Date	09-2022		09-2022	09-2022		
No. of	Batches		•	03			
	DOCUMENTS / DATA	TO BE PROVIDED	D AL	ONG WITH STABIL	ITY STUDY DATA		
1.	Reference of previous appr stability study data of the f		with	N/A			
2.	Approval of API/ DML/0 manufacturer issued by authority of country of orig	concerned regula		T	6104985) valid up to <u>01-08-</u> d & Drug Administration.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).			h 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		R &	Not applicable As per USP monograph method of assay is Titrimetric system			
6.	Record of Digital data log humidity monitoring of s time and accelerated)				cord of digital data logger for dity monitoring of real time by chambers.		
	rks of evaluator: certificate of DS is not valid.						
	on: Approved. Firm shall issuance of registration let		IL/GI	MP certificate of Dru	g Substance manufacturer,		
631.	Name, address of Applicar Authorization Holder	_	I/s Ba ahore	ritish Pharmaceuticals,	23 Km Sheikhupura Road,		
	Name, address of Manufac	~	I/s Ba ahore	ritish Pharmaceuticals,	23 Km Sheikhupura Road,		
	Status of the applicant		 ☑ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver) 		pove (contract giver)		
	GMP status of the firm		DML Renewal granted dated 12-01-2022				
	Evidence of approval of m facility	Li	Capsule (General), approval granted by DRAP (Cent Licensing Board) vide letter No. F. 1-22/2010-Lic(vodated: 12-01-2022				
	Status of application	×	Gen	Generic Drug Product (GDP)			
	Intended use of pharmaceu				omestic sale		
	Dy. No. and date of submission Dy.No			To 23762 dated 21-11-2023			

	Rs. 30,000/- dated 21-08-2023 Slip No. 9961795726
The proposed proprietary name / brand name	Bri-Eso 20mg Capsule
Pharmaceutical ingredient (API) per unit	Each capsule contains: Esomeprazole Coated pellets of magnesium trihydrate each to esomeprazole20mg
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)
	Nexum 20mg Capsule by M/s Getz Pharma Pakistan Karachi (Reg. 033890)
	M/s Vision Pharmaceuticals Plot No. 22-23, Industriangle Kahuta Road, Islamabad.
	Firm has submitted QOS as per WHO QOS-PD temple. Firm has summarized information related to nomenclat structure, general properties, solubility, physical formanufacturer, description of manufacturing process controls, specifications, analytical procedures and validation, batch analysis and justification of specificat reference standard, container closure system and stability studies of drug substance and drug product.
	The firm has submitted detail of nomenclature, struct general properties, solubility, physical form, manufactur description of manufacturing process and controls, tests impurity & related substances, specifications, analyt procedures and its verification, batch analysis justification of specification, reference standard, contactlosure system and stability studies of drug substance
(Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of c substance at both accelerated as well as real time condition. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}$ 75% \pm 5% RH for 6 months. The real time stability data conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months
	The firm has submitted detail of manufacturer, description manufacturing process and controls, specification analytical procedure and its verification studies, by analysis and justification of specification, refere standard, container closure system and stability studies drug product.
comparative dissolution	Firm has submitted Pharmaceutical Equivalence comparative dissolution with Nexum capsule 20mg (CPharma)
	Firm has submitted analytical method validation st reports for drug substance as well as drug product.

		STABILIT	Y STU	DY DATA	
			maceuti		dustrial Triangle Kahuta
API Lot Number EMZ 046548		· · ·			
Descrip	otion of Pack	Capsule with Pur	rple col	ored cap and white bod	y
(Conta	iner closure system)	^		in bleached board unit o	carton UV Coated
Stabilit	y Storage Condition	Real time: 30°C = Accelerated: 40°C			
Time P	Period	Real time: 6 mon Accelerated: 6 m			
Freque	ncy	Accelerated: 0, 3 Real Time: 0, 3,		· ·	
Batch I	No.	B1		B2	В3
Batch S	Size	2000 Capsule	,	2000 Capsule	2000 Capsule
Manufa	acturing Date	10-2022		10-2022	10-2022
No. of	Batches			03	
	DOCUMENTS / DATA	TO BE PROVIDI	ED AL	ONG WITH STABIL	ITY STUDY DATA
1.	Reference of previous appr stability study data of the f		ns with	N/A	
2.				56 valid up to 13-06-2024	
3.	Documents for the procurement of API with approval from DRAP (in case of import). 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			py of locally purchased from	
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 & Submitted audit trail reports on product testing				
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)				dity monitoring of real time
Decisio	on: Approved.				
•	proposed shelf life and on registration application.	accelerated studi	ies for s	ix months as per the c	stability studies throughout ommitment submitted in the es as per the commitment
632.	Name, address of Applican Authorization Holder	ant / Marketing M/s British Pharmaceuticals, 23 Km Sheikhupura Lahore		23 Km Sheikhupura Road,	
	Name, address of Manufac	_	M/s Bı Lahore	ritish Pharmaceuticals,	23 Km Sheikhupura Road,
	Status of the applicant		□ Impo	ufacturer orter volved in none of the al	bove (contract giver)
	GMP status of the firm		DML R	Renewal granted dated 1	2-01-2022

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
D. N 11 6. 1	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	Each capsule contains:
Pharmaceutical ingredient (API) per unit	Esomeprazole Coated pellets of magnesium trihydrate eq
Di di di di di di di di di di di di di di	to esomeprazole40mg
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, Industr Triangle Kahuta Road, Islamabad.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templar. Firm has summarized information related to nomenclatural structure, general properties, solubility, physical for manufacturer, description of manufacturing process a controls, specifications, analytical procedures and validation, batch analysis and justification of specification reference standard, container closure system and stabilistudies of drug substance and drug product.
Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure general properties, solubility, physical form, manufactured description of manufacturing process and controls, tests impurity & related substances, specifications, analytic procedures and its verification, batch analysis a justification of specification, reference standard, contain 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 dr substance at both accelerated as well as real time condition. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ 75% \pm 5% RH for 6 months. The real time stability data conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.

	Pharmaceutical Equivalence and comparative dissolution		analyti analysi	cal procedure and its s and justification d, container closure sy	d controls, specifications, verification studies, batch of specification, reference estem and stability studies of
			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.		
		STABILIT	Y STU	DY DATA	
Manuf	Facturer of API	M/s Vision Phar Road, Islamabad		icals Plot No. 22-23, Inc	lustrial Triangle Kahuta
API L	ot Number	EMZ 046535			
	ption of Pack iiner closure system)	*		ored cap and white bod in bleached board unit o	•
Stabili	ty Storage Condition	Real time: 30°C : Accelerated: 40°C			
Time I	Period	Real time: 6 mor Accelerated: 6 m			
Freque	ency	Accelerated: 0, 3 Real Time: 0, 3,			
Batch	No.	B1		B2	В3
Batch	Size	2000 Capsule	2	2000 Capsule	2000 Capsule
Manuf	facturing Date	10-2022		10-2022	10-2022
No. of	Batches			03	
	DOCUMENTS / DATA	TO BE PROVID	ED AL	ONG WITH STABIL	ITY STUDY DATA
1.	Reference of previous appr stability study data of the f		ns with	N/A	
2.	Approval of API/ DML/GMP certificate manufacturer issued by concerned regauthority of country of origin.			· · · · · · · · · · · · · · · · · · ·	
3.	Documents for the procurement of Alapproval from DRAP (in case of import).		I with	Firm has submitted copy of locally purchased from M/s Vision Pharmaceuticals dated 30-09-2022	
4.	Data of stability batches will be suppo attested respective documents like chromat Raw data sheets, COA, summary data sheet		grams,		
5.	Compliance Record of HI audit trail reports on produ		CFR &	Submitted	
6.					cord of digital data logger for dity monitoring of real time ty chambers.
D	one Annuovad				

- 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 saleDomestic 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

(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 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						
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 24 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. 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 with Azitma 250 tablet (Sami Pharma) Analytical method validation/verification of product STABILITY STUDY DATA				proce justifi	dures and its verific cation of specification,	ation, batch analysis and reference standard, container
Pharmaceutical Equivalence and comparative dissolution Firm has submitted Pharmaceutical Equivalence and comparative dissolution Firm has submitted Pharmaceutical Equivalence and comparative dissolution Firm has submitted Pharmaceutical Equivalence and comparative dissolution Firm has submitted analytical method validation study product Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug substance as well as drug product. Firm has submitted analytical method validation study reports for drug sub		(Conditions & duration of Stability studies) Module-III Drug Product:		The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 24 months. 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		
comparative dissolution with Azitma 250 tablet (Sami Pharma) Analytical method validation/verification of 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) Stability Storage Condition Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Accelerated: 6 months Accelerated: 6 months Frequency Accelerated: 6 months Real time: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) Batch No. B1 B2 B3 Batch Size 500 Tablets 500 Tablets Manufacturing Date 08-2022 08-2022 08-2022 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) 2. Approval of API / DML/GMP certificate of API manufacturer issued by concerned regulators 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, Rawdata sheets, COA, summary data sheets etc. 5. Compliance Record of HPLC software 21CFR & Submitted						
STABILITY STUDY DATA Manufacturer of API		1	valence and	comp	arative dissolution with	
Manufacturer of API			tion/verification			
DML No. 000429(Semi Basic) API Lot Number AZM 2207001 Description of Pack (Container closure system) Stability Storage Condition Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Accelerated: 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 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) 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 approval from DRAP (in case of import). Batch Size AZM 2207001 Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Accelerated: 6 months Accelerated: 6 months Accelerated: 6 months Accelerated: 6 months Accelerated: 6 months Accelerated: 60°C 40°C 175% ± 5%RH Accelerated: 60°C 40°C 175% ± 5%RH Accelerated: 60°C 5% + 5%RH Accelerated: 60°C 5% + 5%RH Accelerated: 60°C 5% + 5%RH Accelerated: 60°C 5% + 5%RH Accelerated: 60°C 5% RH Accelerated: 60°C 5% ± 5%RH Accelerated: 60°C 5% RH Accelerated: 60°C 5% RH Accelerated: 60°C 5% RH Accelerated: 60°C 65% ± 5%RH Accelerated: 60°C 65% ± 5%RH Accelerated: 60°C 65% + 5%RH Accelerated: 60°C 65% + 5%RH Accelerated: 60°C 65% + 5%RH Accelerated: 60°C 65% + 5%RH Accelerated: 60°C 65% + 5%RH Accelerated: 60°C 65% + 5%RH Accelerated: 60°C 65% + 5%RH Accelerated: 60°C 65% + 5%RH Accelerated: 60°C 65% + 5%RH Accelerated: 60°C 65% + 5%RH Accelerated: 60°C 65% + 5%RH Accelerated: 60°C 65% + 5%RH Accelerated: 60°C 65% + 5%R			STABILIT	TY ST	UDY DATA	
Description of Pack (Container closure system) Stability Storage Condition Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH Time Period Real time: 6 months Accelerated: 6 months Frequency Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) Batch No. B1 B2 B3 Batch Size 500 Tablets 500 Tablets 500 Tablets 500 Tablets 500 Tablets Manufacturing Date 08-2022 08-2022 08-2022 08-2022 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) 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 withority of mapproval 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. 5. Compliance Record of HPLC software 21CFR & Submitted	Manufa	acturer of API				
Stability Storage Condition Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	API Lo	t Number	AZM 2207001			
Accelerated: 40°C ± 2°C / 75% ± 5%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 500 Tablets Manufacturing Date 08-2022 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) 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. 5. Compliance Record of HPLC software 21CFR & Submitted			Alu-Alu Blister			
Frequency Accelerated: 6 months Real Time: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months) Batch No. B1 B2 B3 Batch Size 500 Tablets 500 Tablets 500 Tablets 500 Tablets Manufacturing Date 08-2022 08-2022 08-2022 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) 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. 5. Compliance Record of HPLC software 21CFR & Submitted	Stabilit	y Storage Condition				
Real Time: 0, 3, 6 (Months)	Time P	eriod				
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) 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. 5. Compliance Record of HPLC software 21CFR & Submitted	Freque	ncy			*	
Manufacturing Date 08-2022 08-2022 08-2022	Batch N	No.	B1		B2	В3
No. of Batches 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. Compliance Record of HPLC software 21CFR & Submitted	Batch S	Size	500 Tablets		500 Tablets	500 Tablets
DOCUMENTS / DATA 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. 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 & Submitted	Manufa	acturing Date	08-2022		08-2022	08-2022
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. 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 & Submitted	No. of	Batches			03	
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. 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 & Submitted		DOCUMENTS / DATA	TO BE PROVID	ED A	LONG WITH STABIL	ITY STUDY DATA
manufacturer issued by concerned regulatory authority of country of origin. 54697225495 Dated 09-03-2023 inspection dated 03-03-2023 issued by DRAP Lahore 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 Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. Compliance Record of HPLC software 21CFR & Submitted	1.			ons witl	n N/A	
approval from DRAP (in case of import). 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. 5. Compliance Record of HPLC software 21CFR & Submitted	2.	manufacturer issued by concerned regulate			atory 54697225495 Dated 09-03-2023 inspection dated	
attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. 5. Compliance Record of HPLC software 21CFR & Submitted	3.	_		PI witl	**	
1		attested respective documents like chromatogram		ograms s etc.	,	
	5.	•		CFR &	Submitted	

5.	Record of Digital data logger for temperat humidity monitoring of stability chambe time and accelerated)	ture and Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	
Decisio	on: Approved.		
•	Manufacturer will place first three prod proposed shelf life and on accelerated stud- registration application.	luction batches on long term stability studies throughout dies for six months as per the commitment submitted in the tion of first three batches as per the commitment submitted	
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, phoo nagar, Kasur-55050 DML No. 000429(Semi Basic)	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template	

Module-III Drug Substance:		Firm has summarized informa structure, general properties manufacturer, description of controls, specifications, and validation, batch analysis and reference standard, container studies of drug substance and of	, solubility, physical form, manufacturing process and dytical procedures and its justification of specification, closure system and stability	
		The firm has submitted detail general properties, solubility, plescription of manufacturing properties and its verifical justification of specification, closure system and stability stream.	physical form, manufacturers, process and controls, tests for es, specifications, analytical ation, batch analysis and reference standard, container	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)		and the data of 3 batches of drug as well as real time conditions. is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / The real time stability data is 6 ± 5% RH for 24 months.	
Module-III Drug Product:		The firm has submitted detail of manufacturing process and analytical procedure and its analysis and justification standard, container closure sydrug product.	d controls, specifications, s verification studies, batch of specification, reference	
	Pharmaceutical Equivalence and comparative dissolution		naceutical Equivalence and A Zetro tablet 500mg (Getz	
Analytical method of product	validation/verification	Firm has submitted analytical method validation study reports for drug substance as well as drug product.		
	STABILI	ΓΥ STUDY DATA		
Manufacturer of API	M/s Citi pharma DML No. 0004	a pvt. Ltd. 3km head balloki roa 29(Semi Basic)	d, phool nagar, Kasur-55050	
API Lot Number	AZM 2207001			
Description of Pack (Container closure system)	Alu-Alu Blister			
Stability Storage Condition		$C \pm 2^{\circ}C / 65\% \pm 5\%RH$ $C \times 2^{\circ}C / 75\% \pm 5\%RH$		
Time Period	Real time: 6 mo			
Frequency Accelerated: 0, Real Time: 0, 3				
Batch No.	B1	B2	В3	
Batch Size 500 Tablets		500 Tablets	500 Tablets	
Manufacturing Date	08-2022	08-2022	08-2022	
No. of Batches		03		
DOCUMENTS / DA	ATA TO BE PROVID	DED ALONG WITH STABIL	ITY STUDY DATA	
1. Reference of previou stability study data o	s approval of application f the firm (if any)	ons with N/A		

2.	* *	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.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

- 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.

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 DM No. 000973 (Formulation) dated 18-10-2023 specifying Eye/Ear Drops (General) section. Firm has submitted copy of letter of Issuance of New DM No. 000973 (Formulation) dated 18-10-2023 specifying Eye/Ear Drops (General) section.	
Evidence of approval of manufacturing facility		
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 Ciprofloxacin3mg	
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 authorities	regulatory	CILOXAN (USFDA Approved)
	For generic drugs (me-t	too status)	Rocip Eye Drop 0.3% of Remington Pharmaceutical Industries (Reg.No. 015693)
Module-II (Quality Overall Summary)		PI manufacturer.	Zhejiang Xinhua Pharmaceutical Co., Ltd Zhejiang Provincial chemical and medical materials base linhai zone, linhai, Zhejiang, China
		erall 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.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Pharmaceutical Equivalence		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.
			Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $65\% \pm 5\%$ RH for 36 months.
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
			Firm has submitted pharmaceutical equivalence of their product against Rocip Eye Drop 0.3% of Remington Pharmaceutical Industries.
			Firm has submitted analytical method validation study reports for drug substance as well as drug product.
		STABILIT	TY STUDY DATA
Manuf	acturer of API	Zhejiang Provincial Zhejiang, China	armaceutical Co., Ltd chemical and medical materials base linhai zone, linhai,
API Lo	ot No.	ZCFX21-015	
	ption of Pack iner closure system)	Packed in 5 ml D polypropylene cap.	rop-Tainer LDPE bottle and plug with a polystyrene or
Stabili	Stability Storage Condition Real time: 30°C ± 2° Accelerated: 40°C ±		

Time Period		Real time: 6 months Accelerated: 6 months			
Frequency	1	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No.	CP-TB01ED	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	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.		
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.		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	M/S Zenith Chemical Industries (Pvt) Ltd,				
Zhejiang Provincial chemical and medical	Lahore Pakistan				
materials base linhai zone, linhai, Zhejiang, China					

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 DN No. 000973 (Formulation) dated 18-10-2023 specifyi Liquid Ampoule (General) section.	
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Issuance of New DMI 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 Injection5 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 templated Firm has summarized information related to nomenclatured structure, general properties, physical form, manufacturers description of manufacturing process and controls specifications, analytical procedures, conductivity, and it validation, batch analysis and justification of specifications container closure system and drug product.	
Module-III Drug Substance:	Firm has submitted detailed drug substance data related t nomenclature, structure, general properties, physical form manufacturers, description of manufacturing process an controls, specifications, analytical procedures and it 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 it description, composition, pharmaceutical developmen manufacture, manufacturing process and process contro process validation protocols, control of excipients, control of	

			drug 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 vali product	dation/verification of	Firm has submitted an reports for drug product.	alytical method validation study	
		STABILIT	ΓΥ STUDY DATA		
Man	ufacturer 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			
	cription of Pack ntainer closure system)	5ml Clear glass amp	ooules		
Stab	ility Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}$ Accelerated: $40^{\circ}\text{C} \pm$			
Time	e Period	Real time: 6 months Accelerated: 6 mont			
Freq	uency	Accelerated: 0, 3, 6 (Neal Time: 0, 3, 6 (Nea			
Batc	h No.	WFI-TB-001	WFI-TB-002	WFI-TB-003	
Batc	h Size	3000 Ampoules	3000 Ampoules	3000 Ampoules	
Man	ufacturing Date	05-2023	05-2023	05-2023	
Date	of Initiation	17-05-2023	17-05-2023	17-05-2023	
No.	of Batches		03		
	DOCUMENTS / DA	TA TO BE PROVID	ED ALONG WITH STA	ABILITY STUDY DATA	
1.	Reference of previous a with stability study data of		ns Not Applicable		
2.			PI 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 was approval from DRAP (in case of import).		th Not Applicable		
4.	Data of stability batches will be supported attested respective documents li chromatograms, Raw data sheets, COA, summa data sheets etc.		ke	alytical record for product testing.	
5. Compliance Record of HPLC software 21CFR audit trail reports on product testing		& Not Applicable			
6.	6. Record of Digital data logger for temperature a humidity monitoring of stability chambers (retime and accelerated)				
Deci	sion: 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 DMI 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 DMI 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 Ciprofloxacin200mg		
	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 Bosci Pharmaceuticals Pvt. Limited.		
	Name and address of API manufacturer.	Zhejiang Guobang Pharmaceutical Co., Ltd (abbreviated a ZJGB) No. 6, weiwu Road, Hangzhou Gulf Shangy Economic and Technological Development Zone, Zhejina 312369, China		
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templated Firm has summarized information related to nomenclature structure, general properties, solubilities, physical form manufacturers, description of manufacturing process and controls, specifications, analytical procedures and it validation, batch analysis and justification 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		

	Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product:		process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \pm 5\%$ RH for 36 months. Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
	Pharmaceutical Equiva	lence		armaceutical equivalence of their ox Infusion (Reg. 048423) of M/s Pvt. Limited.	
	Analytical method vali product	dation/verification of		alytical method validation study e as well as drug product.	
		STABILIT	TY STUDY DATA		
Manu	nfacturer 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 I	Lot No.	DK21-2111224			
	ription of Pack tainer closure system)	100ml glass vial			
Stabi	lity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time	Period	Real time: 6 months Accelerated: 6 months			
Frequ	nency		ccelerated: 0, 3, 6 (Months) eal Time: 0, 3, 6 (Months)		
Batch	n No.	CP-TB 001	CP-TB 002	CP-TB 003	
Batch	n Size	300 Bottles	300 Bottles	300 Bottles	
Manu	ifacturing 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		ABILITY 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 A manufacturer issued by concerned regulate authority of country of origin.				
3. Documents for the procurement of API w approval from DRAP (in case of import).		th Firm has stated that Pharmaceutical Pvt. L			

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.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

- 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	M/s Shangyu Jingxin Pharmaceutical Co., Ltd.		
(abbreviated as ZJGB) No. 6, weiwu Road,	No. 31 Weisan Road, Hangzhou Bay, Shangyu,		
Hangzhou Gulf Shangyu Economic and	Shangyu Economic and Technological		
Technological Development Zone, Zhejinag	Development Area, China.		
312369, China			

Decision: The board deferred the case for the submission of short comings communicated.

	The board deferred the ease for the basinession of short commission.		
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	

Strength / concentration of drug of Active	Each 100 ml vial contains Levofloxacin
Pharmaceutical ingredient (API) per unit	Hemihydrate500 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 (M 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. Econ Development Zone of Sanmen Country, Zhe 317100,P.R. China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD temporal properties, solubilities, physical manufacturers, description of manufacturing process controls, specifications, analytical procedures and validation, batch analysis and justification of specifications reference standard, container closure system and states studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance data relat nomenclature, structure, general properties, solubil physical form, manufacturers, description of manufact process and controls, specifications, analytical process and its validation, batch analysis and justification specification, reference standard, container closure sy 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 substance at both accelerated as well as real time condit. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 27^{\circ}\text{C} \pm 5\%$ RH for 6 months. The real time stability deconducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.
Module-III Drug Product:	Firm has submitted data of drug product including description, composition, pharmaceutical development manufacture, manufacturing process and process comprocess validation protocols, control of excipients, continuous product, specifications, analytical procedivalidation of analytical procedures, batch analytication of specifications, reference standard materials, container closure system and stability.
Pharmaceutical Equivalence	Firm has submitted pharmaceutical equivalence of product against Leflox Infusion of M/s Getz Pharma Ltd.
Analytical method validation/verification of product	Firm has submitted analytical method validation reports for drug substance as well as drug product.

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			
	cription of Pack ntainer closure system)	100ml glass vial			
Stab	oility Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Tim	e Period	Real time: 6 months Accelerated: 6 months			
Frec	quency	Accelerated: 0, 3, 6 (Neal Time: 0, 3, 6 (Nea			
Bato	ch No.	LF-TB-001	LF-TB-002	LF-TB-003	
Bato	ch Size	30 L	30 L	30 L	
Mar	nufacturing Date	05-2023	05-2023	05-2023	
Date	e of Initiation	02-06-2023	02-06-2023	02-06-2023	
No.	of Batches		03		
	DOCUMENTS / DA	TA TO BE PROVID	ED ALONG WITH ST.	ABILITY 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.				
3.			Newton Health Car	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.		ke		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		& Analysis performed of 21 compliant	on HPLC system which is not CFR	
6.	. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)				

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:

nejiang East-Asia Pharmaceutical Co., Ltd.	Zhejiang East-Asia Pharmaceutical Co., Ltd.			
conomic Development Zone of Sanmen ountry, Zhejiang 317100,P.R. China	Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China Copy of GMP shows validity till 15-08-2021			
ecision: Registration Board deferred the case for submission of reply to the above cited shortcomings				
39. 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 DMI 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 B121000mcg			
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 Pharmaceutica (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, Nort Circle, Shijiazhuang, Hebei, China Secondary ref. standar use from this. API Manufacturer as per Module 3 Sichuan Province Yuxin Pharmaceutical Co., Ltd No. 51 West Section of Changjiang Road, Shifang Economi Development Zone (Southern District), Sichuan.			

Module-II (Quality Ove	Module-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 $40^{\circ}C \pm 2^{\circ}C$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}C \pm 2^{\circ}C$ / $65\% \pm 5\%$ 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 valid 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	o. of Batches 03				

	DOCUMENTS / DATA TO BE PROVIDEI	O 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.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	As per USP Monograph analysis was performed using UV Spectrophotometer.
6.		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		
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.		
The stability data for batch no. VT-TB-001		

Firm response

This is to inform you that the API Manufacturer of Vitamin B12 (Cyanocobalamin) is $\underline{M/s}$. 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.

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		
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 DMI No. 000973 (Formulation) dated 18-10-2023 specifying Eye/Ear Drops (General) section.		
Evidence of approval of manufacturing facility	Plot # B/66-A, S.I.T.E, Noori abad District Jamshord Pakistan M/s Al Barakat Pharmaceutical Industries Plot # B/66-A, S.I.T.E, Noori abad District Jamshord Pakistan Manufacturer Firm has submitted copy of letter of Issuance of New DM. No. 000973 (Formulation) dated 18-10-2023 specifyin Eye/Ear Drops(General) section. Firm has submitted copy of letter of Issuance of New DM. No. 000973 (Formulation) dated 18-10-2023 specifyin Eye/Ear Drops(General) section. Generic Drug Product (GDP) Domestic and Export sales January 18th, 2024, 2:21 pm PKR 30,000/- Dated Dec 19, 2023 4:32 PM Challan No. 108672030604 Almox Eye Drop 0.5% Pe Each ml contains: Moxifloxacin Hydrochloride as Moxifloxacin5mg Antibiotic Eye Drops, Solution USP 5 ml As per SRO Vigamox (USFDA Approved) Moxigan 0.5% Sterile Ophthalmic Solution Of M/s Barrett Hodgson Pakistan (Pvt) Ltd.,Karachi (Reg.No. 042111) Module 1 M/s Shankus Pharma Pvt. Ltd Plot No. 9,10,11, Mila Industrial Estate, Vadsar Road, Santej, Tal; Kalol, Dis Gandhinagar, Gujarat, India M-2 API Manufacturer: M/s Orex Pharma Pvt. Ltd. C/O Cureworth Drugs an		
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			
The proposed proprietary name / brand name	Almox Eye Drop 0.5%		
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit			
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)	Of M/s Barrett Hodgson Pakistan (Pvt) Ltd., Karachi		
Name and address of API manufacturer.	M/s Shankus Pharma Pvt. Ltd Plot No. 9,10,11, Mila Industrial Estate, Vadsar Road, Santej, Tal; Kalol, Dis Gandhinagar, Gujarat, India M-2 API Manufacturer:		
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templat Firm has summarized information related to nomenclatur structure, general properties, solubilities, physical form manufacturers, description of manufacturing process ar		

Module-III Drug Substance:		validation, batch analysi	analytical procedures and its s and justification of specification, ainer closure system and stability and drug product.	
		nomenclature, structure physical form, manufact process and controls, sp and its validation, bat	iled drug substance data related to general properties, solubilities, urers, description of manufacturing eccifications, analytical procedures ch analysis and justification of standard, container closure system rug substance.	
	(Conditions & duration of Stability studies)		lity study data of 3 batches of drug ated as well as real time conditions. data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / nths. The real time stability data is / 65% \pm 5% RH for 36 months.	
Module-III Drug Product:		description, composition manufacture, manufacture process validation protocol drug product, specification of analytic	al procedures, batch analysis, ications, reference standard or	
Pharmaceutical Equiva	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 vali	Analytical method validation/verification of product		Firm has submitted analytical method validation study reports for drug substance as well as drug product.	
	STABILI	TY STUDY DATA		
Manufacturer of API				
API Lot No.	Mox 21103			
Description of Pack (Container closure system)	-	nish colour clear solution filled in 5ml drop trainer LDPE olystyrene or polypropylene cap.		
Stability Storage Condition Real time: 30°C ± 2° Accelerated: 40°C ±				
Time Period Real time: 6 months Accelerated: 6 mont		hs		
Frequency Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (No. 2)				
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 / DA	TA TO BE PROVII	DED ALONG WITH STA	ABILITY STUDY DATA	
1. Reference of previous a with stability study data		ons 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).	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.		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	Not submitted
Health Care Pvt. Ltd Karachi for requisite API.	
Submit copy of valid GMP certificate from API	Not submitted
manufacturer abroad.	
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 Zenith Chemical Industries (Pvt) Ltd,			
M/s Shankus Pharma Pvt. Ltd Plot No. 9,10,11,	Lahore Pakistan			
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				

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 \pm 2°C / 75% \pm 5% RH for 6 months. The real time stability data is conducted at 30°C \pm 2°C / 65% \pm 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.		
	_		Firm has submitted Pharmaceutical Equivalence and comparative dissolution with Doudart Capsule of Gsk.		
	Analytical method validation/verification of product			has submitted analytics for drug substance as w	
		STABILIT	Y STU	JDY DATA	
Industrial Tria Dutasteride by		Industrial Triang Dutasteride by M	drochloride by M/s Vision Pharmaceuticals Plot No. 22-23, gle Kahuta Road, Islamabad. M/s Softgel Health Care (Pvt) Ltd Survey No: 20/1, Vendalur road, Pudupakkam Village, Kancheepuram District		
API Lo	ot Number				
	ption of Pack iner 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			
Stabilit	y Storage Condition	Real time: 30°C Accelerated: 40°		65% ± 5%RH C / 75% ± 5%RH	
Time P	Period	Real time: 6 mor Accelerated: 6 m			
Freque	ncy	Accelerated: 0, 3 Real Time: 0, 3,			
Batch 1	No.	T001		T002	T003
Batch S	Size	1000 Capsule	s	1000 Capsules	1000 Capsules
Manufa	acturing Date	11-2022		11-2022	11-2022
No. of	Batches			03	
	DOCUMENTS / DATA	TO BE PROVID	ED AL	ONG WITH STABIL	ITY STUDY DATA
1.	Reference of previous approval of applications with stability study data of the firm (if any)		ns with	N/A	
2.	Approval of API/ DML/GMP certificate of A		ulatory	Addl.Dir.(QA<-1)-56 valid up to 13-06-2024	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		I with		
4.	Data of stability batches will be supported attested respective documents like chromatogram. Raw data sheets, COA, summary data sheets etc.		grams,		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		CFR &	Our HPLC system is n	ot 21 CFR compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)				dity monitoring of real time
Remarks of evaluator:					
	Shortcomings/Deficiencies Valid GMP certificate from both API manufacturers			rm reply ibmitted	

Copy of agreement between manufacturer and API	We have used Tamsulosin pellets and Dutasteride soft
supplier.	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.

- 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:- Calcitriol1mcg		
	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		

			1			
				validation, 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:		manufa proced justific	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 Equivocomparative dissolution	valence and		has submitted Pharm tor product	naceutical Equivalence with	
	Analytical method valida of product	tion/verification		nas submitted analytic for drug product.	cal method validation study	
		STABILI	TY STU	JDY DATA		
API L	ot Number	042951				
	iption of Pack ainer closure system)	with solution for	or injecti		ass USP type-1 Ampoule filled leach board pack containing 5	
Stabili	ity Storage Condition		$\pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ $^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time 1	Period	Real time: 6 mc				
Freque	ency	Accelerated: 0, Real Time: 0, 3				
Batch	No.	CL050		CL051	CL052	
Batch	Size	1000 Ampoul	les	1000 Ampoules	1000 Ampoules	
Manut	facturing Date	07-2023		07-2023	07-2023	
No. of	Batches			03		
	DOCUMENTS / DATA	TO BE PROVII	DED AL	ONG WITH STABILI	TY STUDY DATA	
1.	Reference of previous appropriate stability study data of the f		ons with	N/A		
2.	Approval of API/ DML/omanufacturer issued by authority of country of original	concerned reg				
3.	Documents for the procurement of API approval from DRAP (in case of import).		PI with	with Copy of DRAP clearance submitted dated 11-07-2023		
4.	Data of stability batches will be support attested respective documents like chromatog Raw data sheets, COA, summary data sheets		ograms,	Submitted		
5.	Compliance Record of HPLC software 210 audit trail reports on product testing		CFR &			
6.	Record of Digital data logger for temperate humidity monitoring of stability chamber time and accelerated)				cord of digital data logger for idity monitoring of real time ity chambers.	
Decisi	on: 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.

	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: Mecobalamin0.5mg		
	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 $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\%$ $\pm 5\%\text{RH}$ for 48 months and accelerated at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$ $\pm 5\%\text{RH}$ 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 validated of product			has submitted analytic for drug product.	cal method validation study	
		STABILIT	TY STU	JDY DATA		
	ner closure system)	Alu-PVC Blister	r packe	d in card board unit car	rton	
Stabilit	y Storage Condition	Real time: 30°C: Accelerated: 40°C		65% ± 5%RH C / 75% ± 5%RH		
Time P	eriod	Real time: 6 mor Accelerated: 6 m				
Freque	ncy	Accelerated: 0, 3 Real Time: 0, 3,				
Batch N	No.	MC 011		MC012	MC013	
Batch S	Size	1000 Tablets	1	1000 Tablets	1000 Tablets	
Manufa	acturing Date	07-2023		07-2023	07-2023	
No. of 1	Batches		03			
	DOCUMENTS / DATA	TO BE PROVID	ED AI	ONG WITH STABILI	TY STUDY DATA	
1.	Reference of previous appressibility study data of the		ns with	N/A		
2.	Approval of API/ DML/ manufacturer issued by authority of country of ori	concerned regi				
3.	Documents for the procapproval from DRAP (in c		I with	with Copy of DRAP clearance submitted dated 23- 06-2021		
4.	Data of stability batches attested respective docume Raw data sheets, COA, su	ents like chromato	ograms,			
5.	Compliance Record of Hi audit trail reports on produ		CFR &	FR & HPLC System is not 21 CFR Compliant		
6.	Record of Digital data log humidity monitoring of time and accelerated)					
Decisio	n: 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 registra		Т			
644.	Name, address of Applica Authorization Holder	nt / Marketing	Marketing M/s Safina Pharmaceutical (Pvt) Ltd, 17 km. Sheikhupu Road, Lahore			
	Name, address of Manufa	cturing site.	M/s Safina Pharmaceutical (Pvt) Ltd, 17 km. Sheikhupura Road, Lahore			
	Status of the applicant					

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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$. 75% \pm 5% RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$. 65% \pm 5% RH for 36 months.
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.		
	comparative dissolution			Firm has submitted Pharmaceutical Equivalence and comparative dissolution with Risek Capsule 40mg (Getz Pharma)		
	Analytical method validated of product	ation/verification		has submitted analytic for drug substance as v	cal method validation study well as drug product.	
		STABILIT	TY STU	DY DATA		
Manufa	acturer of API	M/s Vision Phar Road, Islamabac		icals Plot No. 22-23, In	dustrial Triangle Kahuta	
API Lo	ot Number	OMP1218				
	otion of Pack iner closure system)	2Alu-Alu Bliste	rs, 7Cap	osule/Blister, in Unit Ca	arton	
Stabilit	y Storage Condition	Real time: 30°C Accelerated: 40°		65% ± 5%RH C / 75% ± 5%RH		
Time P	eriod eriod	Real time: 6 mor				
Freque	ncy	Accelerated: 0, 3 Real Time: 0, 3,		*		
Batch I	No.	TR-016		TR-017	TR-018	
Batch S	Size	1500 Capsulo	e	1500 Capsule	1500 Capsule	
Manufa	acturing Date	08-2022		08-2022	08-2022	
No. of	Batches		03			
	DOCUMENTS / DATA	TO BE PROVID	ED AL	ONG WITH STABIL	ITY STUDY DATA	
1.	Reference of previous appressability study data of the f		ns with	N/A		
2.	Approval of API/ DML/manufacturer issued by authority of country of original	concerned reg				
3.	Documents for the pro- approval from DRAP (in c		I with	Firm has submitted copy of locally purchased from M/s Vision Pharmaceuticals dated 14-06-2022		
4.	Data of stability batches attested respective docume Raw data sheets, COA, sur	ents like chromato	ograms,	Submitted		
5.	Compliance Record of Haudit trail reports on produ		CFR &	Submitted		
6.				Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Decisio	on: Approved.					
 Manufacturer will place first three production batches on long term stability studies through proposed shelf life and on accelerated studies for six months as per the commitment submitted in registration application. Manufacturer will perform process validation of first three batches as per the commitment. 					commitment submitted in the	
645.	Name, address of Application 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. Sheikhupu 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 pelle 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, Industr Triangle Kahuta Road, Islamabad.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templated from the summarized information related to nomenclated structure, general properties, solubility, physical for manufacturer, description of manufacturing process a controls, specifications, analytical procedures and validation, batch analysis and justification of specification reference standard, container closure system and stabilistudies of drug substance and drug product.
Module-III Drug Substance:	The firm has submitted detail of nomenclature, structure general properties, solubility, physical form, manufactured description of manufacturing process and controls, tests impurity & related substances, specifications, analytic procedures and its verification, batch analysis a justification of specification, reference standard, contain 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 disubstance at both accelerated as well as real time condition. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} + 5\% \pm 5\%$ RH for 6 months. The real time stability data conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 36 months.

	Pharmaceutical Equivalence and comparative dissolution		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		
				has submitted Pharm rative dissolution with	naceutical Equivalence and Risek Capsule 20mg (Getz
	Analytical method valida of product			has submitted analytic for drug substance as w	al method validation study vell as drug product.
		STABILIT	TY STU	JDY DATA	
Manu	facturer of API	M/s Vision Phar Road, Islamabac		icals Plot No. 22-23, Inc	dustrial Triangle Kahuta
API L	ot Number	OMP1218			
	iption of Pack ainer closure system)	2Alu-Alu Blister	rs, 7Ca _l	psule/Blister, in Unit Ca	rton
Stabil	ity Storage Condition		$2 \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ $2^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time	Period	Real time: 6 mor			
Frequ	ency	Accelerated: 0, 3 Real Time: 0, 3,			
Batch	No.	TR-013		TR-014	TR-015
Batch	Size	1500 Capsulo	e	1500 Capsule	1500 Capsule
Manu	facturing Date	08-2022		08-2022	08-2022
No. o	f Batches		03		
	DOCUMENTS / DATA	TO BE PROVID	ED AL	ONG WITH STABIL	ITY STUDY DATA
1.	Reference of previous appr stability study data of the f		ns with	N/A	
2.	Approval of API/ DML/0 manufacturer issued by authority of country of orig	concerned reg			
3.	Documents for the procurement of AF approval from DRAP (in case of import).		I with	Firm has submitted copy of locally purchased from M/s Vision Pharmaceuticals dated 14-06-2022	
4.	Data of stability batches will be support attested respective documents like chromate Raw data sheets, COA, summary data sheets		ograms,		
5.	Compliance Record of HPLC software 21 audit trail reports on product testing		CFR &	& Submitted	
6.	humidity monitoring of time and accelerated)			Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	
Decis	ion: 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 submitted in the registration application.	of first three batches as per the commitment	
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 Vonoprazan10mg	
	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 drug product.	studies of drug substance and	
	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 (Conditions & duration o		of drug substance at the time conditions. The conducted at 40°C ± months. The real time	tability study data of 3 batches both accelerated as well as real e accelerated stability data is ± 2°C / 75% ± 5% RH for 6 e stability data is conducted at 5% RH for 24 months	
	Module-III Drug Product	:	its description, codevelopment, manufated and process control, control of excipient specifications, analytical procedures of specifications, ref	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
	Pharmaceutical Equiva Dissolution Profile	lence and Comparative	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 valida	tion/verification of product	Firm has submitted analytical method validation study reports for drug product.		
		STABILITY STU	JDY DATA		
Manufa	cturer of API		ceutical Co Ltd. Jiangxi Fengxin Industrial Park, e Peoples Republic of China		
API Lot	No.	20211101BD			
	tion of Pack ner closure system)	Alu-Alu Blister in unit	carton		
Stability	Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / \text{Accelerated}$: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / \text{C}$			
Time Period Real time: 3 months Accelerated: 3 months					
Frequen	су	Accelerated: 0, 3(Month Real Time: 0, 3 (Month	The state of the s		
Batch N	lo.	277DS01	277DS02	277DS03	
Batch S	ize	2500 Tablet	2500 Tablet	2500 Tablet	
Manufa	cturing Date	02-2022	02-2022	02-2022	
Date of Initiation 22-02-2022			22-02-2022	22-02-2022	

No. of	Batches			03
	DOCUMENT	S / DATA TO BE PROVIDED AL	ONG WIT	H STABILITY STUDY DATA
1.	•	revious approval of applications with data of the firm (if any)	N/A	
2.		issued by concerned regulatory		submitted copy of GMP Certificate (No. dated 20-01-2022 Validity 19-01-2027.
3.		r the procurement of API with DRAP (in case of import).	dated 22-13 0.75Kg of	submitted copy of commercial invoice 2-2021 cleared on 24-01-2022 specifying Vonoprazan Fumarate. The invoice is AD (I&E) DRAP, Karachi.
4.	attested respect	ity batches will be supported by ive documents like chromatograms, s, COA, summary data sheets etc.	Submitted	for initial and 3 rd month time points.
5.	•	ecord of HPLC software 21CFR & ts on product testing	Not submi	itted
6.		toring of stability chambers (real	temperatur	ubmitted record of digital data logger for e and humidity monitoring of real time rated stability chambers.
	ks of Evaluator			
S. No		Observations/Deficiencies/ Short		Response of the Firm
1.	3.2.S.4.1	Copy of the Drug substance specif Drug Product manufacturer is requ	ired.	Submitted
2.	3.2.S.4.2	Analytical procedures used for test Drug substance /Active Phart Ingredient by Drug Product manurequired.	maceutical	Submitted
3.	3.2.P.8	Accelerated and real time stability s is submitted till 3 rd month time poi both accelerated and real time da months supported by attested documents like chromatograms, sheets, COA, summary data sheets Compliance Record of HPLC 21CFR & audit trail reports of testing	nt, provide ta upto 06 respective Raw data etc.	Submitted
Decisio	n: Approved.	testing		
•	Manufacturer proposed shelf registration ap Manufacturer	life and on accelerated studies for splication.	six months a	long term stability studies throughout as per the commitment submitted in the aree batches as per the commitment
647.	Name, address of Applicant / Marketing Authorization Holder		M/s Aspin Pharma Private Limited, Plot # 10 & 25 Main Korangi Industrial road, Sector 20, Korang Industrial Area, Karachi.	
	Name, address	of Manufacturing site.	Main Kor	n Pharma Private Limited, Plot # 10 & 25, rangi Industrial road, Sector 20, Korangi 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 Vonoprazan20mg
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

	1					
			conducted at 40°C ±	accelerated stability data is 2°C / 75% ± 5% RH for 6 e stability data is conducted at 5% RH for 24 months		
	Module-III Drug Product:		its description, co development, manufa and process control, control of excipient specifications, analyt analytical procedures	development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials,		
	Pharmaceutical Equivaled Dissolution Profile	ence and Comparativ	their product again Takecab Tablet 20mg Firm has submitted against the innovate 20mg (batch No. 513	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 validati	on/verification of produ	ct Firm has submitted study reports for drug	analytical method validation product.		
		STABILITY ST	UDY DATA			
Manufa	acturer of API		naceutical Co Ltd. Jiangx nce Peoples Republic of	ti Fengxin Industrial Park, China		
API Lo	t No.	20211101BD				
	otion of Pack ner closure system)	Alu-Alu Blister in uni	carton			
Stabilit	y Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$				
Time P	eriod	Real time: 3 months Accelerated: 3 months				
Freque	ncy	Accelerated: 0, 3(Mor Real Time: 0, 3 (Mont				
Batch N	No.	278DS01	278DS02	278DS03		
Batch S	Size	2500 Tablet	2500 Tablet	2500 Tablet		
Manufa	acturing 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)		h N/A			
2.	* *	concerned regulator		opy of GMP Certificate (No2022 Validity 19-01-2027.		
3.	Documents for the pro- approval from DRAP (in c		dated 22-12-2021 clear 0.75Kg of Vonopraza	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.	attested respecti	ty batches will be supported by ive documents like chromatograms, COA, summary data sheets etc.	Submitted for 3 rd month time point only.			
5.		cord of HPLC software 21CFR & ts on product testing	Not submi	tted		
6.		toring of stability chambers (real	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.			
Remar	ks of Evaluator:					
S. No	Sections	Observations/Deficiencies/ Short	-comings	Response of the Firm		
1.	3.2.S.4.1	Copy of the Drug substance specif Drug Product manufacturer is requ	•	Submitted		
2.	3.2.S.4.2	Analytical procedures used for test Drug substance /Active Phar Ingredient by Drug Product manurequired.	maceutical	Submitted		
3.	3.2.P.8	Accelerated and real time stability s is submitted till 3 rd month time poi both accelerated and real time da	nt, provide	Submitted		

months supported by attested respective documents like chromatograms, Raw data

• Compliance Record of HPLC software 21CFR & audit trail reports on product

sheets, COA, summary data sheets 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.

Routine application of Form 5F (human) cases

testing

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. ☑ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)		
	Status of the applicant			
	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 Fumarate10mg
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ 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.			
	Analytic product		lidation/verification	of	Subm	itted	
	·		STABILITY S	TUI	OY D	ATA	
Manu	facturer of	API	Jiangxi Synergy Phar Fengxin Jiangxi Prov				xi Fengxin Industrial Park, China
API I	Lot No.		20210801BD				
	ription of P ainer closu		Alu-Alu Blister in un	it ca	ırton		
Stabil	lity Storage	Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$				
Time	Period		Real time: 3 months Accelerated: 3 month	ıs			-
Frequ	iency		Accelerated: 0, 3(MorReal Time: 0, 3 (Mor				
Batch	No.		22VPL001		22	VPL002	22VPL003
Batch	Size		2000 Tablet		200	00 Tablet	2000 Tablet
Manu	facturing I	Date	04-2022		0	04-2022	04-2022
Date	of Initiation	1	14-04-2022		14	14-04-2022 14-04-2022	
No. o	f Batches			03			
	DOCU	MENTS / DATA	TO BE PROVIDED A	ALC)NG V	WITH STABIL	ITY STUDY DATA
1.	stability	study data of the f					
2.	manufac		concerned regulator				opy of GMP Certificate (No2020 valid upto 11-03-2025.
3.		ents for the proc l from DRAP (in c	urement of API wi ase of import).	th	Not su	ıbmitted	
4.	attested	respective docume	will be supported but the supported but the support of the support	•	Submi	tted for initial ar	nd 3 rd month time point only.
5.	_	ance Record of HF il reports on produ	PLC software 21CFR ct testing	& N	Not su	ıbmitted	
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)						
	erks of Eva		Gioinnaina/Chart	·i	<u>. </u>	Eine Danle	1
S. No	Sections	Observations/De	eficiencies/ Short-com	ung	8	Firm Reply	
1.	1.3.5		report/ GMP certificat			GMP certification	ate dated 22-01-2024 is
		manufacturing ur years shall be sub	nit issued within the la omitted.	ast tl	nree	submitted.	
		Evidence of approval of manufacturing facturing approved section from Licensing Authority					
2.	3.2.S.7		eal time stability studie			Submitted upto	36 months

		drug substance is submitted, submit real time					
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 3 rd 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.				
D	Designer Amproved						

- 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 Fumarate20mg
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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \pm 5\%$ 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.

					agains Tablet 156) ii	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.		
	Analytica product	l method va	lidation/verification	of	Submi	tted		
			STABILITY ST	TUI	DY DA	TA		
Manu	facturer of A	API	Jiangxi Synergy Phar Fengxin Jiangxi Prov				ki Fengxin Industrial Park, China	
API I	Lot No.		20210801BD					
	ription of Pac ainer closure		Alu-Alu Blister in un	it ca	arton			
Stabil	ity Storage (Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$					
Time	Period		Real time: 3 months Accelerated: 3 month	ıs				
Frequ	ency		Accelerated: 0, 3(Mo Real Time: 0, 3 (Mon		,			
Batch	No.		22VPH001		22V	/PH002	22VPH003	
Batch	Size		2000 Tablet		200	0 Tablet	2000 Tablet	
Manu	facturing Da	ite	04-2022		04	1-2022	04-2022	
Date	of Initiation		20-04-2022		20-0	04-2022	20-04-2022	
No. o	f Batches					03		
	DOCUM	IENTS / DATA	TO BE PROVIDED A	AL (ONG V	VITH STABIL	ITY STUDY DATA	
1.		e of previous appr tudy data of the f	oval of applications wi	th				
2.	manufacti		concerned regulator				opy of GMP Certificate (No2020 valid upto 11-03-2025.	
3.		ts for the proc from DRAP (in c	urement of API with ase of import).	th	Not sul	bmitted		
4.	attested re	espective docume	will be supported but the supported but the supported but the support of the supp		Submit	ted for initial ar	nd 3 rd month time point only.	
5.		ce Record of HI reports on produ	PLC software 21CFR of testing	& 1	Not sul	bmitted		
6.	humidity monitoring of stability chambers (real time and accelerated)							
Rema S.	rks of evalu Sections		Deficiencies/ Short-co	mir	108	Firm Reply		
No		Obsci vations/1		·41111	150	тин керіу		
1.	1.3.5		spection report/ GMP certificate			GMP certific	cate dated 22-01-2024 is	
		manufacturing unit issued within the las years shall be submitted. Evidence of approval of manufacturing fa						
		approved section	on from Licensing Auth	hori	ty.			
2.	3.2.S.7	Only 09-month	real time stability stu	dies	s data	Submitted upt	o 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 3 rd 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.

- 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

coated tablet, word "variant" is engraved on one side and the other side is plain Reference to Finished product specifications Proposed Pack size As per SRO Proposed unit price As per SRO The status in reference regulatory authorities 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, manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of substances, specifications, analytical procedures and its verification, batch analysis and justification of substances, specifications, analytical procedures and its verification, batch analysis and justification of substances, specifications, analytical procedures and its verification, batch analysis and justification of substances, specifications, analytical procedures and its verification, batch analysis and justification of substances, specifications, analytical procedures and its verification, batch analysis and justification of substances.		
Intended use of pharmaceutical product □ Domestic sale □ Export sale	Evidence of approval of manufacturing facility	DRAP (Central Licensing Board) vide letter No. F.
Dy. No. and date of submission Dy. No. and date of submission Dy. No 25509 dated 08-09-2022 Stip No. 710134869597 The proposed proprietary name / brand name Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Levofloxacin 250mg Tablet Each film coated tablet contains: Levofloxacin Hemihydrate eq. to Levofloxacin250mg 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 Proposed Pack size As per SRO Proposed unit price As per SRO The status in reference regulatory authorities Levofloxacin 250mg Tablet (USFDA Approved) Mys Getz Pharma (Pvt.) Limited, Karachi Mys 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 propecties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, statch analysis and justification of specification, specifications, analytical procedures and its verification, batch analysis and justification of specification, batch analysis and justification of specification, tester of drug substance and drug product. The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturing procedures and its verification, batch analysis and justification of specification, reference standard, container closure sy	Status of application	
Details of fee submitted Rs. 30,000/- dated 02-09-2022 Slip No. 710134869597 The proposed proprietary name / brand name Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each film coated tablet contains: Levofloxacin Hemihydrate eq. to Levofloxacin250mg Pharmacotherapeutic Group of (API) Quinolone Antibiotic ATC code: J01MA12 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 Proposed Pack size As per SRO Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Leflox Tablets 250mg (Reg. No.: 026164) of M/s Getz Pharma (Pvt.) Limited, Karachi 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, general properties, solubility, physical form, manufacturer and its validation, batch analysis and justification of specifications, analytical procedures and its validation, batch analysis and justification of process and controls, specifications, analytical procedures, and drug product. 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 verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturers, description of manufacturers, description of specification, reference standard,	Intended use of pharmaceutical product	☐ Export sale
Slip No. 710134869597 The proposed proprietary name / brand name Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Levofloxacin Hemihydrate eq. to Levofloxacin250mg Pharmacotherapeutic Group of (API) Quinolone Antibiotic ATC code: 101MA12 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 Proposed Pack size As per SRO Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) 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, manufacturing processes and controls, specification, analytical procedures and of specification 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, manufacturer, description of specification, reference standard, container closure system and stability studies of drug substance and drug product. 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, specification, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance of process and controls, tests for impurity & related substances, specification, page substance.	Dy. No. and date of submission	Dy.No 25509 dated 08-09-2022
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Pharmacotherapeutic Group of (API) 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 Proposed Pack size Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Leflox Tablets 250mg (Reg. No. 026164) of M/s Getz Pharma (Pvt.) Limited, Karachi 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, specification, reference standard, container closure system and stability studies of drug substance and drug product.	Details of fee submitted	
Pharmaceutical ingredient (API) per unit Levofloxacin Hemihydrate eq. to Levofloxacin250mg 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 Proposed Pack size As per SRO Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Leflox Tablets 250mg (Reg. No.: 026164) of M/s Getz Pharma (Pvt.) Limited, Karachi 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 of specification, nearescent standard, container closure system and stability studies of drug substance of specification, nearescent standard, container closure system and stability studies of drug substance of specification, nearescent standard, container closure system and stability studies of drug substance	The proposed proprietary name / brand name	Levofloxacin 250mg Tablet
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 Proposed Pack size As per SRO Proposed unit price As per SRO The status in reference regulatory authorities For generic drugs (me-too status) Levofloxacin 250mg Tablet (USFDA Approved) Levofloxacin 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, specification, analytical procedures and its validation, 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, specification, sanalytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance		Levofloxacin Hemihydrate eq. to Levofloxacin
coated tablet, word "variant" is engraved on one side and the other side is plain Reference to Finished product specifications Proposed Pack size As per SRO Proposed unit price As per SRO The status in reference regulatory authorities 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, 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, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance	Pharmacotherapeutic Group of (API)	
Proposed Pack size 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, manufacturing process and controls, tests for impurity & related substances, specification, tests for impurity & related substances, specification, batch analysis and justification of specification, batch analysis and justification of specification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance closure system and stability studies of drug substance closure system and stability studies of drug substance	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
Proposed unit price 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, specification, 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	Reference to Finished product specifications	USP specifications
The status in reference regulatory authorities Levofloxacin 250mg Tablet (USFDA Approved) 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, specifications, analytical procedures and its verifications, 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	Proposed Pack size	As per SRO
For generic drugs (me-too status) Leflox Tablets 250mg (Reg. No.: 026164) of M/s Getz Pharma (Pvt.) Limited, Karachi 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	Proposed unit price	As per SRO
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. 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	The status in reference regulatory authorities	Levofloxacin 250mg Tablet (USFDA Approved)
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	For generic drugs (me-too status)	
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	Name and address of API manufacturer.	Address: Plot No. E-120/119/105/106/104, M.I.D.C. Tarapur, Boisar, Tal-palghar, Dist. Thane
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	Module-II (Quality Overall Summary)	specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and
Stability Studies of Drug Substance Firm has submitted stability study data of 3 batches		, ,
· · · · · · · · · · · · · · · · · · ·	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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ RH for 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 va product	lidation/verification	of		analytical method validation g substance as well as drug	
		STABILITY S	TU	DY DATA		
Manufa	acturer of API		rugs Limited – India ot No. E-120/119/105/106/104, M.I.D.C. Tarapur, Boisar, Talt. Thane 401506 MH India.			
API Lo	t No.	LFC/11010006				
	ner closure system)	10 tablets in Alu-Alu	Bl	isters packed in cardbo	ard unit carton	
Stability	y Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$				
Time Po	eriod	Real time: 6 months Accelerated: 6 month	ıs			
Frequer	ncy	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (Mark)		*		
Batch N	No.	T-001		T-002	T-003	
Batch S	Size	2000 Tablets		2000 Tablets	2000 Tablets	
Manufa	acturing Date	11-2021		11-2021	11-2021	
No. of 1	Batches			03		
	DOCUMENTS / DATA				ITY 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/KOI 11037 012022111 140429) valid up to 18-05-2025 issued by Food & Drug Administration. M.S Bandrakurla Complex, Bandra (E), Mumbai Maharashtra, India.		
3.	Documents for the procapproval from DRAP (in c			Firm has submitted copy of commercial invoice No. EXP/3123/22-21 dated 03-08-2021 cleared on 06-09-		

				ifying 5.00 Kg. The DRAP, Lahore.	invoice is cleared by
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Submitted		
5.	•	Record of HPLC software 21CFR & ports on product testing	Not submi	itted	
6.	humidity mo	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			ligital data logger for toring of real time and
Rema	rks of Evaluat	or:			
S. No	Sections	Observations/Deficiencies/ Short-o	comings	Response of the Fi	rm
1.	1.3.5	GMP inspection report/ GMP certification manufacturing unit issued within the years shall be submitted.		GMP inspection r 2022	eport dated 05-12-
2.	3.2.S.4.1	Copies of the Drug substance specific Drug Product manufacturer is required.	•	Submitted	
3.	3.2.S.4.2	Analytical procedures used for testing of the Drug substance by Drug Product manufacture 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.		formulation as refer	t they use same rence product of M/s Care UK as per Accord UK Cellulose Microcrystalline Povidone Cross povidone Magnesium stearate Silica colloidal anhydrous
5.	3.2.P.8	Compliance Record of HPLC software audit trail reports on product testing		Submitted	_

- 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 Levofloxacin500mg
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 sid 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. Than 401506 MH India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-P template. Firm has summarized information related to nomenclature, structure, general properties solubility, physical form, manufacturer, description of manufacturing process and control specifications, analytical procedures and invalidation, 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 nomenclatur structure, general properties, solubility, physic form, manufacturers, description of manufacturing process and controls, tests for impurity & relate substances, specifications, analytical procedures at its verification, batch analysis and justification

	T				
			•	specification, reference standard, container closure system and stability studies of drug substance	
	Stability Studies of Drug S (Conditions & duration of		of drug substance at time conditions. The conducted at 40°C months. The real times	stability study data of 3 batches both accelerated as well as real e accelerated stability data is $\pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 he stability data is conducted at 5% RH for 60 months.	
	Module-III Drug Product:		description of manu specifications, and verification studies, of specification, r	nitted detail of manufacturer, facturing process and controls, lytical procedure and its batch analysis and justification eference standard, container tability studies of drug product.	
	Pharmaceutical Equivale Dissolution Profile	nce and Comparati	their product against Tablets (Batch No. Sanofi-Aventis Pakis Firm has submitted to of their product a Tavanic 500mg T	Pharmaceutical Equivalence of at the product Tavanic 500mg AH002) manufactured by M/s stan. Comparative Dissolution Profile gainst the reference product Cablets (Batch No. AH002) as Sanofi-Aventis Pakistan.	
	Analytical method var product	lidation/verification		analytical method validation rug substance as well as drug	
		STABILITY S	ΓUDY DATA		
Manufa	ecturer of API	M/s Aarti Drugs Lim Address: Plot No. E- palghar, Dist. Thane	120/119/105/106/104, M	I.D.C. Tarapur, Boisar, Tal-	
API Lo	t No.	LFC/11010006			
_	ner closure system)	10 tablets in Alu-Alu Blisters packed in cardboard unit carton			
Stability	y Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time Pe	eriod	Real time: 6 months Accelerated: 6 months			
Frequer	ncy	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch N	Vo.	T-001	T-002	T-003	
Batch S	Size	2000 Tablets	2000 Tablets	2000 Tablets	
Manufa	cturing Date	11-2021	11-2021	11-2021	
No. of Batches		03			
	DOCUMENTS / DATA	TO BE PROVIDED A	LONG WITH STABI	LITY STUDY DATA	
1.	Reference of previous approval of applications with stability study data of the firm (if any)		th N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		ry 11037 012022111 14 issued by Food & Dru	NEW-WHO-GMP/CERT/KOl 40429) valid up to 18-05-2025 ag Administration. M.S Bandra- dra (E), Mumbai Maharashtra,	

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.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.	Sections	Observations/Deficiencies/ Short-	Response of the Firm
No	Sections	comings Short-	Response of the Fifth
1	1.3.5	GMP inspection report/ GMP certificate of	GMP inspection report dated 05-12-2022
		the manufacturing unit issued within the	
		last three years shall be submitted.	
2.	3.2.S.4.1	Copies of the Drug substance specifications	Submitted
		by Drug Product manufacturer is required.	
3.	3.2.S.4.2	Analytical procedures used for testing of	Submitted
		the Drug substance by Drug Product	
		manufacturer is required.	
4.	3.2.P.2.1.1	Compatibility studies of the Drug	Firm inform that they use same formulation
		Substance(s) with excipients shall be	as reference product of M/s Accord Health
		provided as the qualitative composition of	Care UK as per following details:
		the formulation is not similar to innovator /	Variant Pharma Accord UK
		reference product.	Avicel Cellulose
			102(known as Microcrystalline
			PVPK30 (Know Povidone
			as povidone)
			Cross povidone Cross povidone
			Magnesium Magnesium
			stearate stearate
			Aerosil 200 Silica colloidal
			(Know as silica anhydrous
			colloidal)
5.	3.2.P.8	Compliance Record of HPLC software	Submitted
		21CFR & audit trail reports on product	
		testing	

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 /	M/s Xeno Biotech Pharma and Devices (Distributors), House
Importer	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, ALEAF 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 Contro 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: Propofol10mg.
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 an justification of specification, reference standard, container closur 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. Hyderaba

	- 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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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 \pm 2°C / 75% RH \pm 5% RH) and Accelerated 6 months (40°C \pm 2°C / 75% RH \pm 5% RH) storage condition

Decision: Approved as per policy of inspection of manufacturer abroad.

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

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 Piroxicam20mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	NSAID

Reference to Finished pro	oduct specifications	Innovator's
Proposed Pack size		As per SRO
Proposed unit price		As per SRO
The status in reference re	egulatory authorities	Brexin Tablet (ANSM France Approved)
For generic drugs (me-to	o status)	Woxicam 20mg Tablet (Warafana Pharmaceuticals) Reg. 072300
Name and address of AP	I manufacturer.	Nantong Jinghua Pharmaceutical Co Ltd No 20, 3 Haibin Road Yanhai Economic Development Zone Rudong Jiangsu China.
		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 Substan	nce:	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 (Conditions & duration o		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 Equival Dissolution Profile	ence and Comparative	
Analytical method va product	lidation/verification of	
STABILITY STUDY DATA		
Manufacturer of API		naceutical Co Ltd No 20, 3 Haibin Road Yanhai Zone Rudong Jiangsu China.

API	Lot No.	20211206			
Description of Pack (Container closure system) Alu-Alu blister					
Stabi	lity Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time	e Period	Real time: 6 months Accelerated: 6 month	ıs		
Frequ	uency	Accelerated: 0, 3, 6 (Meal Time: 0, 3, 6 (Meal			
Batcl	h No.	PBCD-TAB-001	PBCD-TAB-002	PBCD-TAB-003	
Batcl	h Size	1500 Tablet	1500 Tablet	1500 Tablet	
Man	ufacturing Date	10-2023	10-2023	10-2023	
Date	of Initiation	06-10-2023	06-10-2023	06-10-2023	
No. o	of Batches		03		
	DOCUMENTS / DATA	TO BE PROVIDED	ALONG WITH STABI	LITY STUDY DATA	
1.	Reference of previous approstability study data of the f		ith New License		
2.	Approval of API/ DML/manufacturer issued by authority of country of original	concerned regulato	Firm has submitted ma	Firm has submitted manufacturing license of the firm issued by NMPA China valid till 13-09-2025.	
3.			Mont Research Lab da	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.			cord of testing of all batches	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		& Not submitted by the f	ïrm	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			lity monitoring of real time and	
Eval	uation by PEC:				
	Calaria and flam law				
D:	Submit copy of loan lett	er			
Decis	proposed shelf life and the registration applica	on accelerated studiention. form process validation		stability studies throughout he commitment submitted in as per the commitment	
165.	Name, address of Appl Authorization Holder	icant / Marketing		euticals (SMC-Pvt) Ltd. Plot Estate, K.L.P Road, Rahim	
	Name, address of Manut	Cacturing site.		euticals (SMC-Pvt) Ltd. Plot Estate, K.L.P Road, Rahim Yar	
	Status of the applicant		✓ Manufacturer ☐ Importer ☐ Is involved in none	of the above (contract giver)	
			L 13 III VOI VEU III IIOIIC	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 Sodium75mg
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 s drug product.	tudies of drug substance and	
Module-III Drug Substance:		substance data related general properties, manufacturers, descrip and controls, impuriti procedures and its va justification of specif	detailed data for both drug d to nomenclature, structure, solubilities, physical form, ation of manufacturing process ies, specifications, analytical alidation, batch analysis and fication, reference standard, and stability studies of drug	
	(Conditions & duration of Stability studies) Module-III Drug Product: I i i i i i i i i i i i i i i i i i i		ability study data of 3 batches	
Module-III Drug Produc			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
			results of pharmaceutical uality tests for their product tion of Sami Pharma	
T T T T T T T T T T T T T T T T T T T			report of verification of the drug substance. report of verification of the drug product.	
	STABILITY ST	T		
Manufacturer of API	Henan Dongtai Pharma Henan China.	Co Ltd No. 2, Est Ka	ngtai Road, Tangyin Anyang	
API Lot No.	301221227-5			
Description of Pack (Container closure system)	Glass ampoule			
Stability Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mon	,		
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 A	LONG WITH STABII	LITY STUDY DATA	
Reference of previous appropriate stability study data of the f		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.		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)	
• Decis	Submit BMR of the stability batches sion: Approved	
Decis	Sion: Approved Manufacturer will place first three production proposed shelf life and on accelerated studies f the registration application. Manufacturer will perform process validation submitted in the registration application.	of first three batches as per the commitment
Decis	sion: Approved Manufacturer will place first three production proposed shelf life and on accelerated studies f the registration application. Manufacturer will perform process validation	or six months as per the commitment submitted in
•	Manufacturer will place first three production proposed shelf life and on accelerated studies f the registration application. Manufacturer will perform process validation submitted in the registration application. Name, address of Applicant / Marketing	or six months as per the commitment submitted in of first three batches as per the commitment M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim
•	Manufacturer will place first three production proposed shelf life and on accelerated studies f the registration application. Manufacturer will perform process validation submitted in the registration application. Name, address of Applicant / Marketing Authorization Holder	or six months as per the commitment submitted in of first three batches as per the commitment M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan. M/s Naeem Pharmaceuticals (SMC-Pvt) Ltd. Plot No. 95-A, Industrial Estate, K.L.P Road, Rahim Yar

Evidence of approval of manufacturing facility

• Liquid injection ampoule (general) section

Dry powder for injection (cephalosporin) sectionDry powder for suspension (cephalosporin)

Firm has been granted new license dated 26-10-2023

• Dry powder for injection (cephalosporin) section

• Capsule (Cephalosporin) section

Cream / ointment (General) sectionEye drops (General) section.

Liquid injection vial (General) sectionLiquid injection ampoule (general) section

• Capsule (Cephalosporin) section

section

for following sections:Tablet (General) 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 Maleate50 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,

			specifications, analytical procedures,	s, control of drug product, cal procedures, validation of batch analysis, justification of once standard or materials, em and stability.	
	Pharmaceutical Equivalence and Comparative Dissolution Profile		equivalence for the c	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Amrovil Injection of Amros Pharma	
	Analytical method v product	alidation/verification o	analytical method for	report of verification of	
	1	STABILITY S	ΓUDY DATA		
Man	ufacturer of API	Supriya Lifescience L Taluka Ratnagiri Mahr		huram Industrial Area MIDC	
API	Lot No.	SLL/P/0221007			
	cription of Pack ntainer closure system)	Glass ampoule			
Stab	ility Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Tim	e Period	Real time: 6 months Accelerated: 6 months			
Freq	uency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Bato	ch No.	PM-INJ-001	PM-INJ-002	PM-INJ-003	
Bato	ch Size	500 ampoule	500 ampoule	500 ampoule	
Man	ufacturing Date	10-2023	10-2023	10-2023	
Date	e of Initiation	06-10-2023	06-10-2023	06-10-2023	
No.	of Batches		03		
	DOCUMENTS / DATA	A TO BE PROVIDED A	ALONG WITH STABI	LITY STUDY DATA	
1.	Reference of previous app stability study data of the		New License		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		, Firm has submitted ma	nufacturing license of the firm a valid till 13-09-2025.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).			19-03-2021. Firm has also	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			eord of testing of all batches	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Not submitted by the f	irm	
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			•	
Eva	luation 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 Cefadroxil250mg
	Pharmaceutical form of applied drug	Capsule

Reference to Finished product specifications Proposed Pack size Proposed unit price The status in reference regulatory authorities In USFDA however 250mg capsule is discont without specifying the reason for discontinuati For generic drugs (me-too status) Pharmagen Limited 34-Km, Ferozepur Lahore, Pakistan. Name and address of API manufacturer. Henan Dongtai Pharma Co Ltd. No 2 Est K. Road Tangyin Anyang Henan China. Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QO template. Firm has summarized information to nomenclature, structure, general prop solubilities, physical form, manufact description of manufacturing process and justification specification, reference standard, container of system and stability studies of drug substance drug product. Module-III Drug Substance: Module-III Drug Substance: Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Firm has submitted data of drug product inclined substance. Firm has submitted data of drug product inclined substance. Firm has submitted data of drug product inclined substance. Firm has submitted stability study data of 3 be of drug substance. Firm has submitted stability study data of 3 be of drug substance. Firm has submitted stability study data of 7 be drug substance. Firm has submitted stability study data of 7 be drug substance. Firm has submitted stability study data of 7 be drug substance. Firm has submitted stability study data of 7 be drug substance. Firm has submitted stability study data of 7 be drug substance. Firm has submitted stability study data of 7 be drug substance. Firm has submitted feature and stability.	Pharmacotherapeutic Gro	oup of (API)	Cephalosporin	
Proposed Pack size Proposed unit price As per SRO Could not be confirmed. 500mg capsule is awa in USFDA however 250mg capsule is discont without specifying the reason for discontinuati mustical and the confirmed. 500mg capsule is discont without specifying the reason for discontinuati must be planning to the confirmed. 500mg capsule is discont without specifying the reason for discontinuati must be planning to the confirmed. 500mg capsule is discont without specifying the reason for discontinuati must be planning to the confirmed. 500mg capsule is discont without specifying the reason for discontinuati in USFDA however 250mg capsule is discont without specifying the reason for discontinuati in USFDA however 250mg capsule is discont without specifying the reason for discontinuation. Name and address of API manufacturer. Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QO template. Firm has submitted QOS as per WHO QO template. Firm has submitted door impurities, specification, analytical procedure its validation, batch analysis and justification specification, reference standard, container of system and stability studies of drug substance. Firm has submitted detailed data for both substance data related to nomenclature, strue general properties, solubilities, physical manufacturers, description of manufacturing pr and controls, impurities, specifications, and procedures and its validation, batch analysi justification of specification, reference star container closure system and stability studies of substance. Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Firm has submitted data of drug product inclined development, manufacture, manufacturing proper and process control, process validation protection of drug substance. Firm has submitted data of drug product inclined development, manufacture, manufacturing proper specifications, analytical procedures, validation product of drug substance. Firm has submitted results of pharma				
Proposed unit price The status in reference regulatory authorities The status in reference regulatory authorities The status in reference regulatory authorities Could not be confirmed. 500mg capsule is avain USFDA however 250mg capsule is discontinuate without specifying the reason for discontinuate without specifying the reason for discontinuate without specifying the reason for discontinuate without specifying the reason for discontinuate without specifying the reason for discontinuate without specifical pharma Co Ltd. No 2 Est Kr. Road Tangyin Anyang Henan China. Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QO template. Firm has submitted QOS as per WHO QO template. Firm has submitted gors and continuate the specification, batch analysis and justification pecification, batch analysis and justification specification, reference standard, container of system and stability studies of drug substance data related to nomenclature, strugeneral properties, solubilities, physical manufacturers, description of manufacturing product. Firm has submitted dataled data for both substance data related to nomenclature, strugeneral properties, solubilities, physical manufacturers, description of manufacturing strugeneral properties, solubilities, physical manufacturers and istability studies or substance. Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Firm has submitted stability study data of 3 be of drug substance. Firm has submitted attability study data of 3 be of drug substance. Firm has submitted data of drug product inclists description, composition, pharmace development, manufacture, manufacturing procedures, validation analytical procedures, validation analytical procedures, validation analytical procedures, salidation protections, reference standard or mate container closure system and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile Firm has submitted report of verification analytical method for t		Section of the sectio		
The status in reference regulatory authorities Could not be confirmed. 500mg capsule is avain USFDA however 250mg capsule is discontinuative specifying the reason for discontinuation without specifying the reason for discontinuation without specifying the reason for discontinuation without specifying the reason for discontinuation without specifying the reason for discontinuation without specifying the reason for discontinuation without specifying the reason for discontinuation without specifying the reason for discontinuation. Pharmagen Limited 34-Km, Ferozepur Lahore, Pakistan. Name and address of API manufacturer. Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QO template. Firm has summarized information to nomenclature, structure, general proper solubilities, physical form, manufact description of manufacturing process and cortinuation, batch analysis and justification, patch analysis and justification, patch analysis and stability studies of drug substance data related to nomenclature, strugeneral properties, solubilities, physical manufacturers, description of manufacturing properties, solubilities, physical manufacturers, description of manufacturing properties, description of manufacturing properties, solubilities, physical manufacturers, description of properties, solubilities, physical manufacturers, description of properties, solubilities, physical manufacturers, description of data to not properties, solubilities, physical manufacturers, description of data properties, solubilities, physical manufacturers, tructure, description of data properties, solubilities, physical manufacturers,	Proposed unit price A The status in reference regulatory authorities C in			
Name and address of API manufacturer. Henan Dongtai Pharma Co Ltd. No 2 Est Ka Road Tangyin Anyang Henan China. Module-II (Quality Overall Summary) Firm has submitted QOS as per WHO QO template. Firm has summarized information to nomenclature, structure, general proper solubilities, physical form, manufacturing process and cortinance is validation, batch analysis and justification specification, reference standard, container classes and stability studies of drug substance drug product. Module-III Drug Substance: Module-III Drug Substance: Firm has submitted detailed data for both substance data related to nomenclature, strugeneral properties, solubilities, physical manufacturers, description of manufacturing pring and controls, impurities, specifications, analytication of specification, reference state container closure system and stability studies of substance. Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Firm has submitted stability study data of 3 be of drug substance. Firm has submitted data of drug product inclits description, composition, pharmace development, manufacture, manufacturing pring and process control, process validation prote control of excipients, control of drug prospecifications, analytical procedures, validation prote control of excipients, control of drug prospecifications, reference standard or mate container closure system and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile Analytical method validation/verification of product Firm has submitted results of pharmace equivalence for the quality tests for their praginst Dicloran Injection of Sami Pharma container closure system and stability. Firm has submitted report of verification analytical method for the drug grobduct.			Could not be confirmed. 500mg capsule is available in USFDA however 250mg capsule is discontinued without specifying the reason for discontinuation.	
Road Tangyin Anyang Henan China.	For generic drugs (me-to	oo status)	Pharmagen Limited 34-Km, Ferozepur Road Lahore, Pakistan.	
template. Firm has summarized information re to nomenclature, structure, general propersolubilities, physical form, manufact description of manufacturing procedure its validation, batch analysis and justification specification, reference standard, container of system and stability studies of drug substance drug product. Module-III Drug Substance: Module-III Drug Substance: Firm has submitted detailed data for both substance data related to nomenclature, strugeneral properties, solubilities, physical manufacturers, description of manufacturing products and its validation, batch analysis justification of specification, reference star container closure system and stability studies of substance. Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Firm has submitted stability study data of 3 be of drug substance. Firm has submitted data of drug product inclist description, composition, pharmace development, manufacture, manufacturing product inclist description, composition, pharmace development, manufacture, and stability. Pharmaceutical Equivalence and Comparative procedures, batch analysis, justifications, analytical procedures, batch analysis, justifications, analytical procedures of the quality tests for their pragainst Dicloran Injection of Sami Pharma Analytical method validation/verification analytical method for the drug substance. Firm has submitted report of verification analytical method for the drug produ	Name and address of AP	I manufacturer.	Henan Dongtai Pharma Co Ltd. No 2 Est Kangta Road Tangyin Anyang Henan China.	
substance data related to nomenclature, strugeneral properties, solubilities, physical manufacturers, description of manufacturing properties, and controls, impurities, specifications, and procedures and its validation, batch analysing justification of specification, reference stare container closure system and stability studies of substance. Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product: Firm has submitted stability study data of 3 bayes of drug substance. Firm has submitted data of drug product included its description, composition, pharmace development, manufacture, manufacturing properties, control of excipients, control of drug prospecifications, analytical procedures, validation protection of excipients, control of drug prospecifications, reference standard or mate container closure system and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile Pharmaceutical Equivalence and Comparative Dissolution Profile Analytical method validation/verification of product Firm has submitted report of verification analytical method for the drug substance. Firm has submitted report of verification analytical method for the drug product.	Module-II (Quality Over	rall Summary)	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	
(Conditions & duration of Stability studies) Module-III Drug Product: Firm has submitted data of drug product inclits description, composition, pharmace development, manufacture, manufacturing product inclits description, composition, pharmace development, manufacture, manufacturing product inclits description, composition, pharmace development, manufacture, manufacturing product inclients description, composition, pharmace development, manufacture, manufacturing production of excipients, control of drug products, validation analytical procedures, batch analysis, justificat specifications, reference standard or material container closure system and stability. Firm has submitted results of pharmace equivalence for the quality tests for their product analytical method for the drug substance. Firm has submitted report of verification analytical method for the drug product.	Module-III Drug Substan	nce:	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, analytica procedures and its validation, batch analysis and justification of specification, reference standard container closure system and stability studies of drug substance.	
its description, composition, pharmace development, manufacture, manufacturing properties and process control, process validation protects control of excipients, control of drug prospecifications, analytical procedures, validation analytical procedures, batch analysis, justificat specifications, reference standard or matecontainer closure system and stability. Pharmaceutical Equivalence and Comparative Dissolution Profile Pirm has submitted results of pharmace equivalence for the quality tests for their programment against Dicloran Injection of Sami Pharma Analytical method validation/verification of product Firm has submitted report of verification analytical method for the drug substance. Firm has submitted report of verification analytical method for the drug product.	Stability Studies of Drug Substance (Conditions & duration of Stability studies) Module-III Drug Product:		Firm has submitted stability study data of 3 batches of drug substance.	
Dissolution Profile equivalence for the quality tests for their pragainst Dicloran Injection of Sami Pharma Analytical method validation/verification of product Firm has submitted report of verification analytical method for the drug substance. Firm has submitted report of verification analytical method for the drug product.			development, manufacture, manufacturing process and process control, process validation protocols control of excipients, control of drug product specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials	
product analytical method for the drug substance. Firm has submitted report of verification analytical method for the drug product.		lence and Comparative	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Dicloran Injection of Sami Pharma	
STABILITY STUDY DATA	1	alidation/verification of	Firm has submitted report of verification of	
		STABILITY ST	UDY DATA	
nufacturer of API Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan.	ufacturer of API Pharmagen Limited 34-Ki		Km, Ferozepur Road, Lahore, Pakistan.	
Lot No.	Lot No.			

Description of Pack (Container closure system)	Glass ampoule	Glass ampoule		
Stability Storage Condition		Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$		
Time Period Real time: 6 months Accelerated: 6 months				
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No.	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 / DA	TA TO BE PROVIDED	ALONG WITH STABII	LITY STUDY DATA	
Reference of previous approval of applications with New License				

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.	Hirm has submitted convent GMIP certificate issued
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.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted by the firm
6.		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: Paracetamol1000mg
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

	Module-III Drug Substa	nce:	substance data related general properties, manufacturers, descrip and controls, impuriti procedures and its va justification of species	detailed data for both drug I to nomenclature, structure, solubilities, physical form, tion of manufacturing process ies, specifications, analytical alidation, batch analysis and fication, reference standard, m and stability studies of drug
	Stability Studies of Dru (Conditions & duration		Firm has submitted star of drug substance.	ability study data of 3 batches
	Module-III Drug Produc	ct:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
	Pharmaceutical Equiva Dissolution Profile	llence and Comparative	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Acetamol infusion of Seraph pharma	
	Analytical method v product	alidation/verification of	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 ST	UDY DATA	
Manu	ufacturer of API	Pharmagen Limited 34-	Km, Ferozepur Road, La	ahore, Pakistan.
API l	Lot No.	00510941/363/2023		
	ription of Pack tainer closure system)	Glass vial		
Stabi	lity Storage Condition	Real time : $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequ	uency	Accelerated: 0, 3, 6 (Mor Real Time: 0, 3, 6 (Mor	· · · · · · · · · · · · · · · · · · ·	
Batcl	n No.	T-001	T-002	T-003
Batcl	n Size	600 Bottles	600 Bottles	600 Bottles
Manı	ufacturing Date	10-2023	10-2023	10-2023
Date	Date of Initiation 08-10-2023		08-10-2023	08-10-2023
No. o	No. of Batches		03	
		A TO BE PROVIDED A	I	LITY STUDY DATA
1.	Reference of previous app stability study data of the		New License	
2.	Approval of API/ DML/ manufacturer issued by authority of country of ori	concerned regulatory	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	4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
4	5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted by the firm
	6.		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 Acetate0.1mg
		(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		
		☐ 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 Finisho manufacturer	ed product	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 Overa	all 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 Produc	t):	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 valid product	ation / verification of	Method verification studies have submitted including linearity, range, accuracy, precision & specificity.		
		STABILITY ST	TUDY DATA		
Manı	ıfacturer of API	Farmabios S.p.A,			
	Via Pavia 1, Gropello		Cairoli, 27027.		
API I	Lot No.	2142AMO B001192	23		
	ription of Pack	2x10's Alu-PVC			
(Cont	tainer closure system)	1's Alu-PVC			

Stabi	lity Storage Condition	Real time: 30°C ±2° C/RH/ 65% ±5%			
		Accelerated: 40 °C±	2° C /RH 75% <u>+</u> 5%		
Time	Period	Real time: 24 months Accelerated: 6 months			
Freq	uency	Accelerated: 0, 3, 6 (m	onths)		
		Real Time: 0, 3, 6, 9	9. 12, 18, 24 (months)		
Stren	igth	Flurocort Tablet 0.1mg			
Batc	h No.	001	002	003	
Batc	h Size	150000 Tablets	150000 Tablets	150000 Tablets	
Man	ufacturing Date	Oct-2021	Dec-2021	Feb. 2022	
Date	of Initiation	Nov2021	20-12-2021	10.02.2022	
No. o	of Batches		03		
		Administrati	ve Portion		
1.	Reference of previous a with stability study data		Firm has referred last onsite panel inspection for instant dosage form conducted during last two years BAXIB (Apixaban) 2.5mg & 5mg Tablets on 5 th 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/ manufacturer issued by authority of country of o	concerned regulatory	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).		Fludrocortisone Acetate name of FARMABIC Gropello Caroli PV, Ital	dated:05.12.2019 in the OS Via Pavia, 1-27027 y attested by ADC DRAP rm 6 is attached while Form	
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 lo humidity monitoring of time and accelerated)				

Remarks of Evaluator	Response Received from Registration Holder
Qualitative composition of reference product	We have been developed our product with the
i.e., MHRA approved Florinef 0.1mg Tablet by	Reference from Amneal Pharmaceuticals New
Aspen Pharma and applied formulation are	York LLC, Link is given below for your ready
different. Accordingly, Drug-excipient	reference, While, CDP and Pharmaceutical
compatibility studies are required to be	Equivalence were performed against the Florinef
submitted.	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/drugInf
	o.cfm?setid=51363453-6d33-4aee-8426-
	37ac0bf3cc10.
	Drug-Excipient compatibility studies have also
	been submitted.
Description of Container Closure System is not	Now mentioned Container Closure system in
mentioned on provided stability data.	stability data (Please find attached revised
Furthermore, Alu-Alu Blister is mentioned in	stability data), However, Alu-Alu blister was
Stability Study Protocol. Pl. clarify.	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 <u>Animal Drugs @ FDA.</u>
In all dosage forms.

All listed product shows status: Prescription and Approved

Sr.	Manufacturer	Brand Name &	Indication	Target
#		Composition		Animal
1.	Cronus Pharma Specialities	TEVCOCIN-	Treatment of infections of	Dogs
	India Private Limited	chloramphenicol liquid	the respiratory tract, the	
	Sy No: 99/1, M/s GMR	Each milliliter contains 100	urinary tract, and enteritis	
	Hyderabad Aviation SEZ	milligrams of	and tonsillitis caused by	
	L Mamidipalli	chloramphenicol.		

	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.		MYCHEL-VET	Treatment of infections of	Dogs
	333	Portage	INJECTION	the respiratory tract, the	
	St.	Kalamazoo,	Each milliliter contains 100	urinary tract, and enteritis	
	Michigan	49007	milligrams of	and tonsillitis caused by	
			chloramphenicol.	organisms susceptible to	
				chloramphenicol.	

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 <u>Animal Drugs @ FDA</u>

All listed product shows status: Prescription and Approved

Sr.	Manufacturer	Brand Name &	Indication	Target
#		Composition		Animal
1.	Intervet, Inc.	Butazolidin® Bolus	Dogs	Equids :
	2 Giralda	Butazolidin® Tablets	The drug is used for the relief of	Horse
	Farms Madison, New		inflammatory conditions associated	Dog
	Jersey 07940 United		with a musculoskeletal system.	
	States		Horses	
			This drug is used for the relief of	
			inflammatory conditions associated	
			with the musculoskeletal system.	
2.	Intervet, Inc.	Butazolidin®	Horses	Equids :
	2 Giralda	Injectable 20%	It is used for the relief of inflammatory	Horse
	Farms Madison, New	The drug contains 200	conditions associated with the	Dogs:
	Jersey 07940 United	milligrams of	musculoskeletal system.	
	States	phenylbutazone in each	Dogs	
		milliliter of sterile	It is used for the relief of inflammatory	
		aqueous solution.	conditions associated with the	
			musculoskeletal system.	
3.	Intervet, Inc.	Butazolidin® Granules	Horses	Equids :
	2 Giralda	The drug is in granular	For the treatment of inflammatory	Horse
	Farms Madison, New	form. It is packaged to	conditions associated with the	
	Jersey 07940 United	contain 8 grams of	musculoskeletal system.	
	States	phenylbutazone per		
		package.		
4.	Cronus Pharma	Phenylbutazone	Dogs	Dogs
	Specialities India Private	Tablets, USP 100 & 200	For the relief of inflammatory	
	Limited	mg	conditions associated with the	
			musculoskeletal system	

Sy No: 99/1, M/s GMR	Each tablet contains	
Hyderabad Aviation SEZ	100mg & 200	
L Mamidipalli	milligrams	
Village,Shamshabad	Phenylbutazone USP.	
Mandal,		
Ranga Hyderabad,		
Telangana 501218 India		

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

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:

(equivalent to 3.27 mg scopolamine)

(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 .:: <u>CIMAVET</u> ::. <u>Resultados de la búsqueda</u> 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. <u>REGISTRATION OF FREEFOL MCT 1% INJECTION 20ML VIAL (PROPOFOL 10MG/ML).</u>

M/s Ghani Brothers, Karachi application approved in 330th meeting of Registration Board as per following details:-

Name of Importer / Product License	Name of Drug / Composition	Demanded Pack /
Holder & Manufacturer		MRP
M/s Ghani Brothers, 1st Floor, Karimjee	Freefol MCT 1% Injection	20ml vial x10's
Building, Opp HBL Bank, North Napier	20ml Vial (Propofol 10mg/ml)	As per brand leader
Road, Karachi,	Each vial contains:	
MAH & Manufacturer:	Propofol200mg	
Daewon Pharm Co.,Ltd, 24 Jeyakgondan 1-		
gil Hyangnam-eup, Hwaseong-si, Gyeonggi-		
do, Republic of Korea		

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:	Freefol-MCT 1% Injection	5'sx20ml vial
M/s Daewon Pharm. Co., Ltd., 24,	solution for IV Injection/	
Jeyakgongdan 1-gil, Hyangnam-eup,	Infusion (200mg/20ml)	1.3 Usd per Vial
Hwaseong-si, Gyeonggi-do, Republic of	Each 1ml emulsion contains:	
Korea.	Propofol 10mg	
Marketing Authorization Holder:	(Each vial of 20ml contains	
M/s Daewon Pharm. Co., Ltd., 386	200mg of propofol)	
Cheonhodearo, Sungdong-gu, Seoul,		
Republic of Korea		
Decision M-282: Approved with shelf life of	2 years and as per Policy for inst	pection of Manufacturer

Case History:

abroad.

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	FREEFOL-MCT 1% Injection
	solution for IV injection/infusion
Manufacturer:	(200mg/20ml)
M/s Daewon Pharm. Co., Ltd., 24, Jeyakgongdan 1-gil,	Each 1ml emulsion contains:
Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of	Propofol 10mg
Korea.	
Market Authorization Holder:	

M/s	Daewon	Pharm.	Co.,	Ltd.,	386	Cheonhodearo,
Sun	gdong-gu, S	Seoul, Rep	oublic	of Kore	ea	

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 <u>valid till: 19, Feb, 2021.</u>

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 282^{nd} meeting of Registration Board held on $14^{th} - 15^{th}$ 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 282^{nd} meeting of registration Board held on $14^{th} - 15^{th}$ 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		
	packs	Importe	u	packs	Sulu	
Cerezyme						
Powder for concentrate for solution for infusion.	2021	2022	2023	2021	2022	2023
Each unit dose contains:	50	90	50		106	20
Imiglucerase400U						
Reg. No. 107918						

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 (I'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 (I'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	Parameters
	Holder (PLH)	
Diclair-ST 1,500,000 IU Injection	Manufacturer:	Quantities = 2968
Each Vial contains:	M/s BBT Biotech GmbH, Arnold-	vials
Streptokinase1,500,000 IU	Sommerfeld-ring, Baesweilder,	Batch No. P03893
Reg. No. 059023	Germany.	Mfg. Date: 1-1-2023
		Exp Date: 31-12-2025
	PLH.	
	Phare-Belgium, S.A, Schelle,	
	Belgium	

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 332^{nd} 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 - 41 1 028.	Vial	20-Jan-2021

3	107881	Gam-COVID- Vac	AGP Limited, Karachi	Medgamal Branch, FSBI N.F. Gamaleya	Vial (0.5mL)	1-Feb-2021
		Solution for	Karaciii	"National Research	(0.5IIIL)	
		Intramuscular		Center for		
		Injection		Epidemiology and		
		,		Microbiology" of the		
				Ministry of Health of		
				the Russian Federation,		
				18 Gamalei Street,		
				Moscow 123098,		
4	107007	G '1 '	ADADI (D.)	Russia.	DEG	16 F 1 2021
4	107885	Convidecia Vaccine in	AJM Pharma (Pvt) Ltd, Karachi	M/s CanSino Biologics	PFS	16-Feb-2021
		Prefilled	Liu, Karaciii	Inc., Floor 3 and 4, 185 South Ave., TEDA		
		Syringe		West District, Tianjin,		
		Symme		China.		
5	107886	Convidecia	AJM Pharma (Pvt)	M/s CanSino Biologics	Vial	16-Feb-2021
		Vaccine in	Ltd, Karachi	Inc., Floor 3 and 4, 185		
		Vial		South Ave., TEDA		
				West District, Tianjin,		
				China.		
12	107927	Convidecia	AJM Pharma (Pvt)	M/s CanSino Biologics	1's Vial	7-Mar-2021
		Vaccine	Ltd, Karachi	Inc., Floor 3 and 4, 185	(3 doses)	
				South Ave., TEDA		
				West District, Tianjin,		
13	107928	Convidecia	AJM Pharma (Pvt)	China. M/s CanSino Biologics	1's Vial	7-Mar-2021
13	10/928	Vaccine	Ltd, Karachi	Inc., Floor 3 and 4, 185	(10 doses)	/-iviai-2021
		v accine	Liu, Karaciii	South Ave., TEDA	(10 doses)	
				West District, Tianjin,		
				China.		
6	107887	SARS-CoV-2	National Institute	M/s Beijing Institute of	Vial	12-Mar-2021
		Vaccine (Vero	of Health (NIH),	Biological Products		
		Cell),	Islamabad	Co., Ltd., No.6 & 9,		
		Inactivated		Boxing 2"d Road,		
				Economic-		
				Technological		
				Development Area, Beijing, 100176,		
				China.		
7	107888	Gam-COVID-	AGP Limited,	M/s Generium Joint-	Vial	12-Mar-2021
		Vac	Karachi	Stock Company	(3mL)	
		Solution for		(Generium JSC),		
		Intramuscular		601125, Vladimir		
		Injection		Oblast, petushky		
				District, Volginsky, ul.		
				Zavodskaya, bld. 263,		
0	107000	Com COMB	ACD Limited	Russia.	W: a1	10 M - :: 0001
8	107889	Gam-COVID- Vac	AGP Limited, Karachi	M/s Closed Joint Stock	Vial	12-Mar-2021
		Solution for	Karacili	Company "Pharmaceutical	(3mL)	
		Intramuscular		Company" LEKKO,		
		Injection		601125, Vladimir		
				Oblast, Petushky		
				District, Volginsky, ul.		
				Zavodskaya, bld		
				277,279, Russia.		

	10=000					
9	107890	Gam-COVID- Vac Solution for Intramuscular Injection	AGP Limited, Karachi	M/s Open Joint Stock Company Pharmastandard- UfaVITA plant, Republic of Bashkortastan, Ufa, ul.	Vial (3mL)	12-Mar-2021
				Khudaiberdina, 28, Russia.		
10	107891	Gam-COVID- Vac Solution for Intramuscular Injection	AGP Limited, Karachi	M/s Open Joint Stock Company Pharmastandard- UfaVITA 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 For information (Ratification) of the Registration Board.

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 332 nd 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
008300 Dated 24-09-1985	Humulin N, 100IU/mL Vial Each vial contains: Human insulin NPH Isophane Suspension (rDNA Origin)	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.
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).

 $\frac{https://nedrug.mfds.go.kr/pbp/CCBEM01/getList?totalPages=1061\&page=1\&limit=10\&sort=\&sortOrder=\&searchYn=true\&entpName=\%ED\%95\%9C\%EA\%B5\%AD\%EB\%A6\%B4\%EB\%A6\%AC\&mnfctrName=\&mnfctrCountryCode=\&btnSearch=$

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

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	☑ Domestic sale
pharmaceutical	☐ Export sale
product	☐ Domestic and Export sales
For imported	☐ Finished Pharmaceutical product import
products, specify one	☐ Bulk import and local repackaging
the these	☐ Bulk import and local repackaging for export purpose only
D. N. 114 C. 1	T. 1' '1"NOE DMI WIED D 4 1 10 02 2024
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 $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \pm 5\%$ R.H for 24 months. The accelerated stability data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ 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 (Upright) CW00152A (Inverted)
Remarks of Evaluator:	
	COPP indicating product availability in the country of origin an
approval status of product in US to the current Import Policy for	FDA, Registration Board approved the product subject to compliance finished drugs.
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 24 th 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 15 th 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)

For imported products,	⊠Finished Pharmaceutical product import
specify one the these	☐Bulk import and local repackaging
	☐Bulk import and local repackaging for export purpose only
Dy. No. and date of	CTD Dossier
submission	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	Recombinant Human Insulin 100IU/1ml
of drug of Active	
Pharmaceutical ingredient	
(API) per unit	
Dosage form of applied.	Injectable
Drug	Presentation: Vial
Pharma co therapeutic	Anti-Diabetic
Group of (API	Insulin analogues
Reference to Finished	Ph. Eur. Specifications
product 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	Humulin® R for injection in vial
regulatory authorities	Eli Lilly and Company Limited, Indianapolis, USA
For generic drugs (me-too	Humulin® R for injection in vial
status)	Eli Lilly and Company Limited, Indianapolis, USA
Module-II (Quality	Firm has submitted QOS as per WHO. Firm has summarized
Overall Summary)	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 closur
	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 specification
	reference standard or materials, container closure system and
	stability
Name, address of drug	Biocon Limited: 20th KM. Hosur Road, Electronics City, Bangal
substance manufacturer	- 560 100, INDIA
substance manufacturer	Wockhardt Limited H-14/2, M.I.D.C Area, Waluj, Aurangabad -
	431 136, INDIA.
Module-III Drug	Firm has submitted details drug substance data related to
Substance:	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
	drug substance.

Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted that Six month accelerated(5±3°C) and 48-month long term (-20±3°C) 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 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 & rubb stopper which have. excellent resistance to water, moisture and most organic solvents and chemicals also it is fairly good oxygen barrier and have a grestiffness.
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 1 batches. The real time stability study data is conducted at $05^{\circ}C \pm 3^{\circ}C$ 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

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	Firm has attached CoPP No. 01774/2021/H issued on 24 th October
attached (CoPP, Free sale	2021, subject to inspection after two years.
certificate, GMP	Firm has attached Free Sale Certificate 00494/2023/H issued on
certificate)	04 th September 2023, issued by Egyptian Drug Authority.
	Firm has attached GMP Certificate No. 196/2022 issued on 15 th
	March2022, issued by Egyptian Drug Authority.
Details of letter of	Firm has attached sole Agency agreement No. 43/2021 signed by
authorization / sole	both the parties.
agency agreement	
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	⊠Domestic sale
pharmaceutical product	□Export sale
	□Domestic and Export sales
For imported products,	⊠Finished Pharmaceutical product import
specify one the these	☐Bulk import and local repackaging
	☐Bulk import and local repackaging for export purpose only
Dy. No. and date of	CTD Dossier
submission	Dated: 30th Sept. 2021
Details of fee submitted	Dy. No; 30 September 2021
	Rs: 150,000/-
TT1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Dated: 13-08-2021 (Slip No. 707051580)
The proposed proprietary name / brand name	Insulin H Mix 100
Strength / concentration	Human Insulin30IU/ml
of drug of Active	Isophane Human insulin70IU/ml
Pharmaceutical ingredient	
(API) per unit	
Dosage form of applied.	Injectable
Drug	Presentation: Vial
Pharma co therapeutic	Anti-Diabetic
Group of (API	Insulin analogues
Reference to Finished	Ph. Eur. Specifications
product specifications Proposed unit price	As per DPC
Shelf Life	30 Months
Storage Conditions	- Store at 2 °C to 8 °C
Storage Conditions	- Avoid freezing
	- Keep medicine out of reach of children
TTI	H 1: ® 70/20
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	Humulin® 70/30 suspension for injection in vial
status)	Eli Lilly and Company Limited, Indianapolis, USA
Module-II (Quality	Firm has submitted QOS as per WHO. Firm has summarized
Overall Summary)	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

Name, address of drug	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 1. Biocon Limited: 20th KM. Hosur Road, Electronics City,
substance manufacturer	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 ($25^{\circ}C \pm 3^{\circ}C$, $60\%RH\pm 5$) real time stability study ($05^{\circ}C \pm 3^{\circ}C$) 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.

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Con	chus	ion:
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N/A

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-V Clinical	N/A
Remarks of Evaluator	<ul> <li>Bio similarity data as per WHO guideline is required (including analytical studies; Physicochemical Biological and Clinical studies; immunogenicity studies, Pk, PD studies).</li> <li>Stability studies data of 1 batch of Drug product at 0,3,6,9,12,18, 24 months is required.</li> <li>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.</li> <li>Stability studies data of three batches of Drug substance is required.</li> </ul>

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  $3^{\rm rd}$  &  $9^{\rm th}$  month time points.

Stability study report of 3 Drug Substance batches.

Module-IV Non-Clinical

9.	Name, address of Applicant / Importer	M/s. Atlantic Pharmaceuticals, C-1, D13, Sector 16, K.I.A, Karachi.
	Importer	Karaciii.
	Details of Drug Sale	License No: 597
	License of importer	Address: C-1, D13, Sector 16, K.I.A, Karachi. Validity: 24.02.2023
	Name and address of	In Pakistan: M/s. Atlantic Pharmaceuticals, C-1, D13, Sector 16,
	marketing authorization holder	K.I.A, Karachi
		In Egypt: South Egypt Drug Industrial Co. (SEDICO)
		First Industrial Zone – 6 October City– Egypt
	Name, address of	South Egypt Drug Industrial Co. (SEDICO)
	manufacturer(s)	First Industrial Zone – 6 October City– Egypt
	Name of exporting Country	Egypt
	Detail of certificates	Firm has attached CoPP No. 01823/2021/H issued on 24 th October
	attached (CoPP, Free sale	2021, subject to inspection after two years.
	certificate, GMP certificate)	Firm has attached <b>Free Sale Certificate</b> 00761/2021/H issued on 12-Oct-2021, issued by Egyptian Drug Authority.
	certificate)	Firm has attached GMP Certificate No. 196/2022 issued on 15 th
		March2022, issued by Egyptian Drug Authority.
	Details of letter of	Firm has attached sole Agency agreement No. 43/2021 signed by
	authorization / sole	both the parties.
	agency agreement Status of the applicant	□Manufacturer

	⊠Importer
	☐ Is involved in none of the above (contract giver)
Status of application	
Status of application	□New Drug Product (NDP)
	<b>⊠Generic Drug Product (GDP)</b>
Intended use of	<b>⊠Domestic sale</b>
pharmaceutical product	□Export sale
	□Domestic and Export sales
For imported products,	<b>⊠Finished Pharmaceutical product import</b>
specify one the these	
-F y	□Bulk import and local repackaging
	☐Bulk import and local repackaging for export purpose only
Dy. No. and date of	CTD Dossier
submission	Dated: 04 th Nov. 2021
Details of fee submitted	Dy. No; N/A
	Rs: 150,000/-
	Dated: 13-08-2021 (Slip No. 04743111876)
The proposed proprietary	Insulin H Bio NPH
name / brand name	
Strength / concentration	Each ml contains,
of drug of Active	Recombinant Human Insulin 100IU/ml
Pharmaceutical ingredient	Protamine sulfate0.24IU/ml
(API) per unit	Or
	Each ml contains,
	Insulin isophane100 IU
	*The Quantity of protamine sulphate varies according to assay of
	recombinant human insulin and its isophane ratio.
Dosage form of applied.	Injectable
Drug	Presentation: Vial
Pharma co therapeutic	Anti-Diabetic
Group of (API	Insulin analogues
Reference to Finished	Ph. Eur. Specifications
product 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	Humulin® N 100 IU/ml suspension for injection
	Humulin® N 100 IU/ml suspension for injection Eli Lilly and Company Limited, Indianapolis, USA
regulatory authorities	Eli Lilly and Company Limited, Indianapolis, USA
regulatory authorities For generic drugs (me-too	Eli Lilly and Company Limited, Indianapolis, USA  Humulin® N 100 IU/ml suspension for injection
regulatory authorities For generic drugs (me-too status)	Eli Lilly and Company Limited, Indianapolis, USA  Humulin® N 100 IU/ml suspension for injection Eli Lilly and Company Limited, Indianapolis, USA
regulatory authorities For generic drugs (me-too status) Module-II (Quality	Eli Lilly and Company Limited, Indianapolis, USA  Humulin® N 100 IU/ml suspension for injection  Eli Lilly and Company Limited, Indianapolis, USA  Firm has submitted QOS as per WHO. Firm has summarized
regulatory authorities For generic drugs (me-too status)	Eli Lilly and Company Limited, Indianapolis, USA  Humulin® N 100 IU/ml suspension for injection Eli Lilly and Company Limited, Indianapolis, USA  Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties,
regulatory authorities For generic drugs (me-too status) Module-II (Quality	Eli Lilly and Company Limited, Indianapolis, USA  Humulin® N 100 IU/ml suspension for injection Eli Lilly and Company Limited, Indianapolis, USA  Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of
regulatory authorities For generic drugs (me-too status) Module-II (Quality	Eli Lilly and Company Limited, Indianapolis, USA  Humulin® N 100 IU/ml suspension for injection Eli Lilly and Company Limited, Indianapolis, USA  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,
regulatory authorities For generic drugs (me-too status) Module-II (Quality	Eli Lilly and Company Limited, Indianapolis, USA  Humulin® N 100 IU/ml suspension for injection Eli Lilly and Company Limited, Indianapolis, USA  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
regulatory authorities For generic drugs (me-too status) Module-II (Quality	Eli Lilly and Company Limited, Indianapolis, USA  Humulin® N 100 IU/ml suspension for injection Eli Lilly and Company Limited, Indianapolis, USA  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
regulatory authorities For generic drugs (me-too status) Module-II (Quality	Eli Lilly and Company Limited, Indianapolis, USA  Humulin® N 100 IU/ml suspension for injection Eli Lilly and Company Limited, Indianapolis, USA  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
regulatory authorities For generic drugs (me-too status) Module-II (Quality	Eli Lilly and Company Limited, Indianapolis, USA  Humulin® N 100 IU/ml suspension for injection Eli Lilly and Company Limited, Indianapolis, USA  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,
regulatory authorities For generic drugs (me-too status) Module-II (Quality	Eli Lilly and Company Limited, Indianapolis, USA  Humulin® N 100 IU/ml suspension for injection Eli Lilly and Company Limited, Indianapolis, USA  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,
regulatory authorities For generic drugs (me-too status) Module-II (Quality	Eli Lilly and Company Limited, Indianapolis, USA  Humulin® N 100 IU/ml suspension for injection Eli Lilly and Company Limited, Indianapolis, USA  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
regulatory authorities For generic drugs (me-too status) Module-II (Quality	Eli Lilly and Company Limited, Indianapolis, USA  Humulin® N 100 IU/ml suspension for injection Eli Lilly and Company Limited, Indianapolis, USA  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,

	reference standard or materials, container closure system and stability
Name, address of drug substance manufacturer	<ol> <li>Biocon Limited: 20th KM. Hosur Road, Electronics City, Bangalore - 560 100, INDIA</li> <li>Wockhardt Limited H-14/2, M.I.D.C Area, Waluj, Aurangabad – 431 136, INDIA.</li> </ol>
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 $05^{\circ}\text{C} \pm 3^{\circ}\text{C}$ 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 <b>Insulin H^{Bio} NPH 100 IU suspension</b> (recombinant human insulin with protamine sulphate) manufactured by SEDICO Pharmaceutical Co., 6 October City, Egypt, is

	bioequivalent to the reference brand <b>Insulatard® HM suspension</b> (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	<ul> <li>Bio similarity data as per WHO guideline is required (including analytical studies; Physicochemical Biological and Clinical studies; immunogenicity studies, Pk, PD studies).</li> <li>Stability studies data of three batches of Drug substance is required.</li> </ul>	
Decision: Registration Board deferred the case for provision of following:  • Structural comparison with Innovator product as per Guidelines.		
-	y report of 3 Drug Substance batches.	

#### Cases of M/s. Ottoman Pharma deferred in 296th Meeting of Registration Board.

Sr.	Name and address of	M/s Ottoman Pharma	
No.	product manufacturer	10 km, Raiwind Road, Lahore.	
	(Applicant)		
10.	Brand Name +Dosage Form +	OTTO FLU VAC A/B Injectable Emulsion	
	Strength	Avian Influenza Viruses (AIVs) H7 & H9	
Type of Form, Diary No. Date Form-5			
	of R& I & fee	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 /ml0.075ml	
		Inactivated AIV H9N2[Not less than EID ₅₀ 10 ⁹ /ml0.075ml	
	Pharmacological Group	Veterinary vaccine	
	Finished Product Specification	As per Innovators spec.	
	Shelf Life	12 Months (2-8 ^o 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	Not Available as per record	
	Pakistan		
	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.

1.	Name and address of	M/s Ottoman Pharma
	product manufacturer	10 km, Raiwind Road, Lahore.
	(Applicant)	
	Brand Name +Dosage Form +	OTTO ND+H5 Injectable Emulsion
	Strength	Avian Influenza Viruses (AIVs) H5 & New Castle Disease Virus
	Type of Form, Diary No. Date	Form-5
	of R& I & fee	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 640.06ml
		Inactivated AIV H9N2 containing EID ₅₀ not less than 10 ^{7.0} /ml and HAU
		not less than 640.06ml
	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	Not Available as per record.
	Pakistan	
	Remarks of Evaluator (M.	
	Zubair Masood)	
	Decision in 206th Registration R	oard meeting:

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.

- 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.	Name of	Brand Name &	Pack Size	Decision of RB in 297 th Meeting
No.	Manufacturer	Composition		
1	M/s Eli Lilly and	TALTZ Injection 80mg/	1's Prefilled Pen	Keeping in view valid legalized
	Company, Lilly	1mL	(Autoinjector)/	CoPP and approval of USFDA
	Corporate Center,	Each autoinjector	As per SRO	(Reference Regulatory Authority);
	Indianapolis, IN	prefilled pen contains:		Registration Board approved the
	46285, USA	Ixekizumab: 80mg/mL		product subject to compliance of
		Shelf Life:		current Import Policy for finished
		24 months(5°C)		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 283 rd Meeting	<b>Documents submitted by the firm</b>
i.	Application with required fee as per relevant SRO (in case of	Submitted
	similarity/ resemblance with drug, fee will note be required).	
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  $262^{nd}$  meeting as per following details:

as per following details.				
Name of	Name of Drug and	Date of	Documentary	Decision of RB
Manufacturer	Composition & Reg. No.	application / Fee	details	in 262 nd
		status		meeting
M/s	SCIMAX Injection	Dy. No. 202 R&I	Legalized COPP	Registration
GeneScience	Recombinant Human	DRAP dated 143-	No. 2014012	Board deferred
Pharmaceutical	Granulocyte Colony-	2016	dated 25-6-2014	for submission
s Co. Ltd.,	Stimulating Factor Injection		from china.	of biosimilarity
1718 Yueda		Fee deposited	Valid for two	data and valid
Road, High-	Each vial (1ml) contains:	Rs.15000/- dated	years.	legalized CoPP
Tech	Recombinant Human	17-11-2011 + Rs.		by the firm.
Development	Granulocyte Colony	35000/- dated 12-		
Zone,	Stimulating Factor (rhG-	4-2013 +		
Changchun,	CSF)300ug/vial.	Rs.50000/- dated		
Jilin Province,	Reg. No. 072504	13-11-2014		
China	Shelf life. 02years			

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:

NT 1 1 1 1 T	N 1 1 1 0, 1
Non-clinical In-vivo	Non-clinical Studies
Studies c. Biological/	i. Study of anti-leucopenia effect of Scimax in Canis familiaris and Kunming
Pharmacodynamic	hybrid mice in comparison with Filigsment of Kirin Japan
activity	ii. Non-comparative study of effects of Scimax on voluntary activities of mice
d. Non- clinical toxicity as	iii. Non-comparative study of effects of Scimax on cardiovascular system and
determined in one	central nervous system of anesthetic cat
repeat dose toxicity	Toxicology
study	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.

N s.F.3-3/2008-Reg-I(M-214) Government of Pakistan · legaliz Cabinet Division August, 2011 M/s. Morgan Technologies Services, SA-28, 2nd Floor, Shahnaz Arcade, bulk. 158, Shaheed-e-Millat Road, Karachi. SUBJECT:- REGISTRATION OF DRUGS UNDER SECTION OF THE DRUGS ACT 1976 AND RULES 28, 29 AND 30 OF THE DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976.
The drug as per detains given below has been registered in your name subject to the conditions appearing hereinafter:-Packing' S.No. Reg.No. Name of drug (5) & Composition. Approved Shelf Life. 072504 02 years. Scimax Injection Per vial Each vial contains:-Filgrastim (rhGCSF) ..... 300µg (Manufactured by M/s GeneScience Pharmaceuticals Co. Ltd., Changchun, China) CONDITIONS:-The drug(s) shall be imported in compliance to the provision of Drugs Act, 1976 and rules framed thereunder. Every drug shall be imported in sufficient quantity so as to ensure its regular and adequate supply in the market. 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. Colour Scheme of the labels/cartons and packaging material should not resemble with any of the drug(s) which has of have already been registered. One of the complete method of testing of the finished drug(s) (containing full details of all minor and major steps and protocols along with 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.

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	Registration Board took following decisions with regards to
	Suspension in vials for	Curosurf
	Intratracheal	Sterile Suspension (3ml):
	Instillation.	i. Approved the correction in composition of Curosurf Sterile
		suspension 3ml, as per CoPP as under:
	"Each vial contains:	"Each vial contains: Poractant alfa 240mg".
	Poractant alfa	ii. For the traceability of challan the procedure already prescribed
	240mg".	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	60/1 A-XX, Phase-III, Commercial Zone
	Pharmaceutical	Khayaban-e-Iqbal, DHA, Lahore.
	Pvt. Ltd.,	Gowdon Address: 14 Km Multan Road
		Near Thokar Niaz baig Lahore.
New	M/s. Chiesi	<b>Office No:</b> 4, 4 th Floor, Askari Corporate
	Pharmaceutical	Towers, 75/76 D-1, main Boulevard,
	Pvt. Ltd.,	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.	Brand Name and composition	Decision in 316th Registration Board meeting
No.		
1.	Foot and Mouth Disease Trivalent Vaccine,	Keeping in view legalized GMP and FSC
	Inactivated (Strain O + Strain Asia	indicating product availability in country of
	1+ Strain A)	origin and approval of Italy (Reference
		Regulatory Authority); Registration Board
	Each dose contains:	approved the product subject to compliance of
	Inactivated FMD virus type A antigen ≥	current Import Policy for finished drugs.
	6PD50.	The firm shall submit valid legalized GMP
	Inactivated FMD virus type O antigen ≥	certificate before issuance of registration letter.
	6PD50.	Chairman Registration Board is authorized for
	Inactivated FMD virus type Asia 1 antigen ≥	issuance of registration letter after submission of
	6PD50.	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	Office No. 26, 2nd Floor, Aries Plaza, Murree Road, Shamsabad
	Enterprises,	M/ N/ 1 A A A A A A A A A A A A A A A A A A
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. <u>Imported Veterinary Biologicals from Non-Reference Countries:</u>

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	PT VAKSINDO SATWA NUSANTARA (Plant 2) Jl. Barokah Wanaherang,
	Manufacturer and	Gunung putri, Bogor, West Java 16965, Indonesia
	MA Holder	

Name of exporting country	Indonesia
Brand Name +	Vaksimune IBD M + (1000 Doses)
Dosage Form + Strength	Live Vaccine, Freeze Dried
Composition	Each dose of Freeze-Dried Vaccine contains;
-	Infectious Bursal Disease virus of Moulthrop (Intermediate Plus) strain least
Finished product specifications	Indonesian Pharmacopeia
Pharmacological Group	Vaccine
Shelf life	24 Months (Store at 2°C to 8°C)
International	Cambodia, Vietnam, Egypt, Nepal, and Myanmar
availability	DVDGA VIAG. CAV. AV. 1 A . 1 AV. 11
Alternate Products	BURSA-VAC of M/s Merck Animal Health imported by M/s ICI Pakis
already registered in Pakistan	Limited.
Type of Form	Form 5-A
Dy. No.	Dy.No.13255(R&I) DRAP dated 31-05-2022.
Date of Application,	Fee of PKR75,000/- Challan No. 68777644 dated 23-05-2022.
Fee submitted	Differential Fees of PKR75,000/- Challan No. 355387230688 dated 13-09-20
Demanded Price	De-controlled
Pack size	1000 doses
General Documentation	1. Legalized Certificate of Registration and Free Sale Ref. 07017/PI.500/F/12/2020 dated 07-12-2020 issued by Ministry of Agricult
	Directorate General of Livestock and Animal Health Services, Indonesia.  2. Apostille Letter of Authorization Valid till 31-07-2024.
Evaluator	The product monograph is available in British Pharmacopoeia, but
Comments	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	PT VAKSINDO SATWA NUSANTARA (Plant 2) Jl. Barokah Wanaherang,
	Manufacturer and	Gunung putri, Bogor, West Java 16965, Indonesia
	MA Holder	
	Name of exporting	Indonesia
	country	
	Brand Name +	Vaksimune IBD M + (2000 Doses)
	Dosage Form +	Live Vaccine, Freeze Dried
	Strength	
	Composition	Each dose of the Vaccine contains.
		Infectious Bursal Disease virus of Moulthrop (Intermediate Plus) strain at
		least $10^{2.0} EID_{50}$

· · · · · · · · · · · · · · · · · · ·	oduct Indonesian Pharmacopeia
specifications	
Pharmacologica	l Vaccine
Group	
Shelf life	24 Months (Store at 2°C to 8°C)
International	Cambodia, Vietnam, Egypt, Nepal, and Myanmar
availability	
Alternate Pro	ducts BURSA-VAC of M/s Merck Animal Health imported by M/s ICI Pakistan
already register	ed in Limited.
Pakistan	
Type of Form	Form 5-A
Dy. No.	Dy.No.13256(R&I) DRAP dated 31-05-2022.
Date of Applica	
Fee submitted	Differential Fees of PKR75,000/- Challan No. 558806968890 dated 13-09-2023
Demanded Price	
Pack size	2000 doses
General	1. Legalized Certificate of Registration and Free Sale Ref. No.
Documentation	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	The product monograph is available in British Pharmacopoeia, but the
Comments	manufacturer has developed the product as per Indonesian Pharmacopoeia.
1. Decision: Kee	eping 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 Ph	armacopoeia 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	Gunung putri, Bogor, West Java 16965, Indonesia
	MA Holder	
	Name of exporting	Indonesia
	country	
	Brand Name +	VAKSIMUNE NDHV IB (1000 Doses)
	Dosage Form +	Live Vaccine, Freeze Dried
	Strength	
	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	Indonesian Pharmacopeia
	specifications	
	Pharmacological	Vaccine
	Group	
	Shelf life	24 Months (Store at 2°C to 8°C)
	International	Cambodia, Vietnam, Egypt, Nepal, and Myanmar
	availability	

Alternate Products	Gallimune 302 ND IB EDS by M/s Saadat International, contains Inactivated
already registered in	Newcastle Disease virus, Ulster 2C strain.
Pakistan	Hipraviar B1/H120 by M/s Hipra Laboratories, contains Live Infectious Bronchitis
	Virus, attenuated H120 strain
Type of Form	Form 5-A
Dy. No.	Dy.No.13254(R&I) DRAP dated 31-05-2022.
Date of Application,	Fee of PKR75,000/- Challan No. 49617236995 dated 23-05-2022.
Fee submitted	Differential Fees of PKR75,000/- Challan No. 79591888480 dated 13-09-2023
Demanded Price	De-controlled
Pack size	
General	2. Legalized Certificate of Registration and Free Sale
Documentation	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.
<b>Evaluator Comments</b>	• 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 <b>Ulster strain</b> and
	Infectious Bronchitis virus of <b>H120 strain</b> 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.
		The state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the s
	Name of	PT VAKSINDO SATWA NUSANTARA
	Manufacturer and	(Plant 1) Jl. Mercedes Benz No. 12 Cicadas, Gunung Putri, Bogor, West Java
	MA Holder	16964, Indonesia
	Name of exporting	Indonesia
	country	
	Brand Name +	VAKSIMUNE ND L Inaktif 0.1 (5000 Doses)
	Dosage Form +	Inactivated Vaccine in Oil Emulsion
	Strength	macu vacca vaccino in on Emaiston
	Composition	Each dose of the vaccine contains:
	r · · · ·	Newcastle Disease Genotype VII virus of N018 strain at least10 ^{8.3} EID ₅₀
	Finished product	Indonesian Pharmacopeia
	specifications	•
	Pharmacological	Vaccine
	Group	
	Shelf life	24 Months (Store at 2°C to 8°C)
	International	Cambodia, Vietnam, Egypt, Nepal, and Myanmar
	availability	
	Alternate Products	The applied strain is not registered as per data available
	already registered in	
	Pakistan	
	Type of Form	Form 5-A
	<u> </u>	

Dy. No. Date of Application,	Dy.No.13402(R&I) DRAP dated 02-06-2022. Slip Number: 599925048 of PKR150,000/- dated 23-05-2022.
Fee submitted	Shp (valide): 3777230 to 61 (1884130,000) dated 23 03 2022.
Demanded Price	5000 doses
Pack size	Decontrolled
General Documentation	<ul> <li>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.</li> <li>Apostile Letter of Authorization Valid till 31-07-2024</li> </ul>
Evaluator Comments	<ul> <li>The applied strain is not registered as per data available.</li> <li>The product monograph is available in British Pharmacopoeia, but the manufacturer has developed the product as per Indonesian Pharmacopoeia.</li> </ul>

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	PT VAKSINDO SATWA NUSANTARA
	Manufacturer and	(Plant 1) Jl. Mercedes Benz No. 12 Cicadas, Gunung Putri, Bogor, West Java
	MA Holder	16964, Indonesia.
	Name of exporting	Indonesia
	country	
	Brand Name +	VAKSIMUNE ND L Inaktif 0.1 (2000 Doses)
	Dosage Form +	Inactivated Vaccine in Oil Emulsion
	Strength	
	Composition	Each dose of the vaccine contains:
		Newcastle Disease Genotype VII virus of N018 strain at least10 ^{8.3} EID ₅₀
	Finished product	Indonesian Pharmacopeia
	specifications	
	Pharmacological	Vaccine
	Group	
	Shelf life	24 Months (Store at 2°C to 8°C)
	International	Cambodia, Vietnam, Egypt, Nepal, and Myanmar
	availability	
	Alternate Products	The applied strain is not registered as per data available
	already registered in	
	Pakistan	Form 5-A
	Type of Form Dy. No.	
	Dy. No.  Date of Application,	Dy.No.13401(R&I) DRAP dated 02-06-2022. Slip Number: 6732290991 of PKR150,000/- dated 23-05-2022.
	Fee submitted	Sup number. 0/32230331 of FKK130,000/- dated 23-03-2022.
	Demanded Price	2000 doses
	Pack size	Decontrolled
	General	Legalized Certificate of Registration and Free Sale Ref. No.
	Documentation	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.** Imported Human Biologicals from Reference Countries

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 Godown address:  1 st & 2 nd 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:  H. Lundbeck A/S Ottiliavej 92500 Valby_Denmark.
	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.

	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	<ul> <li>☐ Manufacturer</li> <li>☑ Importer</li> <li>☐ Is involved in none of the above (contract giver)</li> </ul>
Status of application	<ul><li>☑ New Drug Product (NDP)</li><li>☐ Generic Drug Product (GDP)</li></ul>
Intended use of pharmaceutical product	<ul><li>☑ Domestic sale</li><li>☐ Export sale</li><li>☐ Domestic and Export sales</li></ul>
For imported products, specify one the these	<ul> <li>☑ Finished Pharmaceutical product import.</li> <li>☐ Bulk import and local repackaging</li> <li>☐ Bulk import and local repackaging for export purpose only</li> </ul>
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: Eptinezumab100mg
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 (metoo 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)	and Long term 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 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 $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\%$ RH $\pm$ 5% RH at 0,1,3 and 6 Months. The long Term stability study data of three batches is conducted at $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$ 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	<ul> <li>Firm has submitted the following data;</li> <li>7 phase-1 studies were conducted in healthy subjects.</li> <li>2 phase-1 studies were conducted in patients with other disease states/conditions.</li> <li>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.</li> <li>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 prigrating.</li> </ul>
Decision	 n: Keening in view ahove	migraine.  ; Registration Board after deliberation, legalized CoPP issued by EMA

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	<ul><li>☑ New Drug Product (NDP)</li><li>☐ Generic Drug Product (GDP)</li></ul>
	Intended use of pharmaceutical product	<ul> <li>☑ Domestic sale</li> <li>☐ Export sale</li> <li>☐ Domestic and Export sales</li> </ul>
	For imported products, specify one the these	<ul> <li>☑ Finished Pharmaceutical product import</li> <li>☐ Buk import and local repackaging</li> <li>☐ Buk import and local repackaging for export purpose only</li> </ul>

Dy. No. and date of	Form -5F Dy. No.:29795
submission	R&I dated: 20/10/2022
D. H. GG. 1. IV. 1	D 150 000
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 / concentration of 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 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 $\pm$ 5°C) at 0,3,6,9,12,18,24,36,48
	and 60 months. Accelerated stability study ( $+5^{\circ}C \pm 3^{\circ}C$ ) at 0,1,2,3 and 6 months. <b>Lutropin Alfa</b> Firm has submitted stability data of 3 batches as;
	Long term stability data (-20°C $\pm$ 5°C) at 0,3,6,9,12,18,24,36,48 and 60 months. Accelerated stability study (+5°C $\pm$ 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 ( $+5^{\circ}C \pm 3^{\circ}C$ ) 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 ( $25^{\circ}C \pm 2^{\circ}C$ 60%RH $\pm$ 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.

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	License No: 0186
	Drug	Address: 7th Floor, Nice Trade Orbit Building, 44-A, Block-6,
	Sale	P.E.C.H.S, Razi Road, Shahrah-e-Faisal, Karachi
	License of importer	<b>Validity:</b> 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)	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 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	<ul><li>☑ New Drug Product (NDP)</li><li>☐ Generic Drug Product (GDP)</li></ul>		
Intended use of pharmaceutical product	<ul> <li>☑ Domestic sale</li> <li>☐ Export sale</li> <li>☐ Domestic and Export sales</li> </ul>		
For imported products, specify one the these	<ul> <li>☑ Finished Pharmaceutical product import</li> <li>☐ Buk import and local repackaging</li> <li>☐ Buk import and local repackaging for export purpose only</li> </ul>		

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	Pergoveris (450 IU+ 225 IU)/0.72 mL Solution for Injection in a		
proprietary name /	Prefilled Pen		
brand name			
Strength / concentration	Each pre-filled pen contains 450 IU (equivalent to 33 micrograms) of		
C	follitropin alfa (r-hFSH) and 225 IU (equivalent to 9 micrograms) of		
of drug of Active Pharmaceutical			
	lutropin alfa (r-hLH) in 0.72 mL.		
ingredie			
nt(API) per unit			
Dosage form of applied	Solution for Injection in a Pre-Filled Pen		
drug			
Pharmacotherapeutic Group of	Gonadotropins		
(API)			
_	Innovator's Specifications		
specifications			
Proposed Pack size	1 Pre-filled Pen + 7 needles		
Proposed Pack size  Proposed unit price	1 Pre-filled Pen + 7 needles As per SRO		
Proposed unit price	As per SRO		
Proposed unit price Shelf Life	As per SRO  12 months		
Proposed unit price	As per SRO		
Proposed unit price Shelf Life	As per SRO  12 months  2–8 °C		
Proposed unit price Shelf Life	As per SRO  12 months		
Proposed unit price  Shelf Life  Storage Conditions	As per SRO  12 months  2–8 °C		
Proposed unit price  Shelf Life  Storage Conditions  The status in reference	As per SRO  12 months  2–8 °C		
Proposed unit price  Shelf Life  Storage Conditions  The status in reference	As per SRO  12 months  2–8 °C  Pergoveris Solution for Injection (EMA)		
Proposed unit price  Shelf Life  Storage Conditions  The status in reference regulatory authorities	As per SRO  12 months  2–8 °C  Pergoveris Solution for Injection (EMA)		
Proposed unit price  Shelf Life  Storage Conditions  The status in reference regulatory authorities  For generic drugs (me-too status)	As per SRO  12 months  2–8 °C  Pergoveris Solution for Injection (EMA)  N/A		
Proposed unit price  Shelf Life  Storage Conditions  The status in reference regulatory authorities  For generic drugs (me-too status)  Module-II (Quality Overall	As per SRO  12 months  2–8 °C  Pergoveris Solution for Injection (EMA)  N/A  The firm has submitted QOS as per ICH guidelines. Firm has		
Proposed unit price  Shelf Life  Storage Conditions  The status in reference regulatory authorities  For generic drugs (me-too status)	As per SRO  12 months  2–8 °C  Pergoveris Solution for Injection (EMA)  N/A  The firm has submitted QOS as per ICH guidelines. Firm has summarized information related to general properties, manufacturers,		
Proposed unit price  Shelf Life  Storage Conditions  The status in reference regulatory authorities  For generic drugs (me-too status)  Module-II (Quality Overall	As per SRO  12 months  2–8 °C  Pergoveris Solution for Injection (EMA)  N/A  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,		
Proposed unit price  Shelf Life  Storage Conditions  The status in reference regulatory authorities  For generic drugs (me-too status)  Module-II (Quality Overall	As per SRO  12 months  2–8 °C  Pergoveris Solution for Injection (EMA)  N/A  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		
Proposed unit price  Shelf Life  Storage Conditions  The status in reference regulatory authorities  For generic drugs (me-too status)  Module-II (Quality Overall	As per SRO  12 months  2–8 °C  Pergoveris Solution for Injection (EMA)  N/A  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		
Proposed unit price  Shelf Life  Storage Conditions  The status in reference regulatory authorities  For generic drugs (me-too status)  Module-II (Quality Overall	As per SRO  12 months  2–8 °C  Pergoveris Solution for Injection (EMA)  N/A  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		
Proposed unit price  Shelf Life  Storage Conditions  The status in reference regulatory authorities  For generic drugs (me-too status)  Module-II (Quality Overall	As per SRO  12 months  2–8 °C  Pergoveris Solution for Injection (EMA)  N/A  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		
Proposed unit price  Shelf Life  Storage Conditions  The status in reference regulatory authorities  For generic drugs (me-too status)  Module-II (Quality Overall	As per SRO  12 months  2–8 °C  Pergoveris Solution for Injection (EMA)  N/A  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		
Proposed unit price  Shelf Life  Storage Conditions  The status in reference regulatory authorities  For generic drugs (me-too status)  Module-II (Quality Overall	As per SRO  12 months  2–8 °C  Pergoveris Solution for Injection (EMA)  N/A  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		

NY 11 C 1	N M 10 0 A
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 $\pm$ 5°C) at 0,3,6,9,12,18,24,36,48 and 60 months. Accelerated stability study (+5°C $\pm$ 3°C) at 0,1,2,3 and 6 months. <b>Lutropin Alfa</b> Firm has submitted stability data of 3 batches as;
	Long term stability data (-20°C $\pm$ 5°C) at 0,3,6,9,12,18,24,36,48 and 60 months. Accelerated stability study (+5°C $\pm$ 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	Endotoxins, Clarity and degree of Opalescence, Compendial, Degree of coloration, osmotic pressure molar concentration, in vivo bioactivity in the drug product, Extractable Volume for Prefilled 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 and accelerated conditions. The real time stability data provided is conducted at ( $+5^{\circ}$ C $\pm$ 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 ( $25^{\circ}$ C $\pm$ 2°C 60%RH $\pm$ 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.
	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
Desistant Variation 1 1 D	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.

2 4.	Name,	address of Applicant /	Martin Dow Specialities (Pvt.) Ltd.
7.	Importer	or ripplicant /	Nice Trade Orbit Building, 44-A, Block-6, P.E.C.H.S., Razi Road, Shahrah-e-Faisal, Karachi, Pakistan.
			Shahan e Faisai, Isalaem, Fakistain.

Details of Drug Sale License of importer	License No: 0186 <b>Address:</b> 7 th 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	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	<ul><li>☑ New Drug Product (NDP)</li><li>☐ Generic Drug Product (GDP)</li></ul>
Intended use of pharmaceutical product	<ul> <li>☑ Domestic sale</li> <li>☐ Export sale</li> <li>☐ Domestic and Export sales</li> </ul>
For imported products, specify one the these	<ul> <li>□ Finished Pharmaceutical product import</li> <li>□ Buk import and local repackaging</li> <li>□ Buk import and local repackaging for export purpose only</li> </ul>

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 / concentration of 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 $\pm$ 5°C) at 0,3,6,9,12,18,24,36,48 and 60 months.  Accelerated stability study (+5°C $\pm$ 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 $\pm$ 5°C) at 0,3,6,9,12,18,24,36,48 and 60 months. Accelerated stability study (+5°C $\pm$ 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 ( $+5^{\circ}C \pm 3^{\circ}C$ ) 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 ( $25^{\circ}C \pm 2^{\circ}C$ 60%RH $\pm$ 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;
	<ul> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ul>

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	S	Panel of Inspector(s)/ Date of inspection
	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/inperson 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/	Name of Drug	Panel of Inspector(s)/ Date of
	Manufacturer & meeting	&Composition	inspection
	number		
1.	M/s. Medi Mark	<ol> <li>Enoxaparin sodium</li> </ol>	i. Mr. Arif Chaudhary,
	Pharmaceuticals, Liaquat	Careparin Injection PFS	Additional Director
	Chowk, Sahiwal.	Each 0.4ml dose contains;	ii. Mr. Salateen Waseem
	Manufacturer:	Enoxaparin	Philip,
	M/s. Dongying Tiandong	sodium4000	Deputy Director
	Pharmaceutical Co., Ltd	AXa IU	06-03-2023 &
	China.		07-03-2023
	(M-312)	2. Enoxaparin sodium	
		Careparin Injection PFS	
		Each 0.4ml dose contains;	
		Enoxaparin	
		sodium4000	
		AXa IU	

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 sodium6000 AXa IU
ii.	Enoxaparin sodium
	Careparin Injection PFS
	Each 0.4ml dose contains;
	Enoxaparin sodium4000 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 331**st **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. <b>156 ICT/2013</b> 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 CVI988at least 3.0log 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	<ul> <li>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.</li> <li>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.</li> <li>iii. No. of doses/ pack is not mentioned in stability studies.</li> <li>iv. Stability study data provided is of only last time point.</li> </ul>

Decision of RB in 312 th meeting	Registration Board deferred the product for submission of following by the firm:
meeting	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, 18months. 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 330 th 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.	

## <u>Imported Veterinary Biological applied by M/s Vety Care (Pvt.) Ltd., deferred in 330th meeting of Registration Board</u>

28.	Name of Applicant	M/s Vety Care (Pvt.) Ltd.,	
		Plot #77, St#6, I-10/3, Islamabad.	
	DSL details	DSL No. <b>156 ICT/2013</b> dated 31-12-2014 valid till 20-12-2022.	
		Product License Holder:	
		M/s Intervet Nederland B.V.	
	Name of Manufacturer and		
	Product License Holder:	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 CVI988at least 3.0log ₁₀ TCID ₅₀	
	Finished Product Specifications	Ph. Eur. Specifications	

	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	<ul> <li>Only Virus Titer has been performed in stability studies. It manufacturer has submitted that only virus titration might chart during stability studies therefore only one test is performed.</li> <li>The firm has applied for two pack sizes against one CoPP while pusizes are not mentioned on CoPP. The firm was asked for evider and the firm submitted that product is available in country of original No. of doses/ pack is not mentioned in stability studies.</li> <li>Stability study data provided is of only last time point.</li> </ul>
Decision of RB in 312 th meeting	Registration Board deferred the product for submission of following the firm:  a. Stability data indicating pack size of the product including parameters as mentioned in finished product specifications appropriate time intervals i.e. 0, 3, 6, 9, 12, 18months.  b. Valid Legalized CoPP indicating desired pack sizes as two differ pack sizes are applied.
Evaluation by DBER  Decision of RB in 330 th	The firm has now provided the stability data of 3 random batches 2000 doses at following time intervals and only virus titration a 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 pasize, including all parameters as mentioned in Finished Prod Specifications for appropriate time intervals, is still not provided Programmed Firm informed that the COPP is on William and pack sizes are not mentioned in COPP. The firm has submitted valid legalized COPP No. 258907 dated March,2023.
meeting	Deferred for submission of stability data of 03 commercial batches applied pack size indicating all parameters as mentioned in Finish Product Specifications and on all time points as recommended by 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 triidentity, sterility, safety, extraneous agents are tested at all these tipoints.

the recommendations of veterinary expert member Registration Board, approved the product subject to compliance to current import policy for finished drug.

# <u>Imported Veterinary Biological applied by M/s Vety Care (Pvt.) Ltd., deferred in 312th meeting of Registration Board</u>

29.	Name of Applicant  M/s Vety Care (Pvt.) Ltd., Plot #77, St#6, I-10/3, Islamabad.		
	DSL details	DSL No. <b>156 ICT/2013</b> 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 11/94at 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°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 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 efficat study 10 ^{2.5} TCID ₅₀ and 10 ^{2.8} TCID ₅₀ dose is used. The firm was asked 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 312 th 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 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  $10^{1.5}$  TCID₅₀ 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} TCID₅₀/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} TCID₅₀/ chick.
  - Study: TRT/97/AVR/177: three inocula:  $10^{3.1}$ ,  $10^{2.0}$ , or  $10^{1.2}$ , TCID₅₀ 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} TCID₅₀/ 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.

# <u>Imported Veterinary Biological applied by M/s Hilton Pharma (Pvt.) Ltd., deferred in 312th meeting of Registration Board</u>

<u>ti atioli Doalu</u>	
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	M/s PT. Medion Farma Jaya Address:
Manufacturer	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 +	Medivac Gumboro A vaccine
Dosage Form +	Freeze dried live vaccine
Strength	
Diary No. Date of	Dy No. 26809 Dated: 12-10-2020, Dy No. 29865 dated 1211-2021
R& I & fee	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	Freeze dried live vaccine against infectious bursal disease / Gumboro
Group	disease in poultry
Type of Form	Form-5A
Finished Product	Ph. Eur. Specifications
Specification	
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.
	Firm has submitted the stability data.
finished product	Medivac Gumboro A (1000 doses) for 24 months stored at 2-8 °C.
innisited product	Batch No. 88B093, 88B094 and 88B095.
Document Details	Legalized Certificate of Pharmaceutical Product (CoPP) No
2 octament Details	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 tits 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 Firm has submitted response via letter no. SA/MN/01032024 on dated 1st BE&R: 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** (1/68), 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	Vietnam	MDI-11	April 2027
	Gumboro A			
2	Medivac	West	TACB 38/07	July 2026
	Gumboro A	Malaysia		
3	Medivac	East	(9)DVS/HQ/700-	December
	Gumboro A	Malaysia	3/1/6	2024
4	Medivac	Cambodia	FR02-003-	May 2025
	Gumboro A		1496/0520	
			BKP-GDAHP	
5	Medivac	Singapore	Registered-04 Juni	October
	Gumboro A		2018	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 address M/s Saadat International and **Importer** 117-Habitat Apartments, Shadman-II, Jail Road, Lahore Detail of DSL International M/sSaadat Address: 117 Habitat Apartments Shadman II, Jail Road, Lahore. Valid till: 24-Feb-2028 Name and address of **Marketing Authorization Holder:** Manufacturer Name: Boehringer Ingelheim and MAH 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 Mexico. exporting country Brand Name +Dosage **VOLVAC BEST AI + ND** Form + Strength Diary No. Date of R& Dy. No. 10583 R&I Dated 27-04-2022 & fee Rs. 150,000/- (Slip No. 51647879232) Each (0.5)Composition Each dose contains: dose mL) contains: Inactivated subunit H5 Hemagglutinin (HA) of High Pathogenic Avian Influenza (HPAI) virus 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 Manufacturer's specifications Specification 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) 1000doses/500ml Pack size Reference Regulatory N/A Authority Availability Noblis Influenza H5N2 (manufacturer: MSD Animal Health) Products already registered in Pakistan 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.

	<u></u>
	• The applied strain (H5N1) is not registered in Pakistan as per available record.
Decision of RB in its 331 st 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	<ul> <li>The firm has submitted the following.</li> <li>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".</li> <li>Legalized GMP Certificate No.R.06/2021 dated 26-11-2021 valid till 20-12-2024.</li> <li>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."</li> <li>Regarding International availability of applied strain, the firm has submitted articles of different journals wherein international availability of applied strain is not confirmed.</li> </ul>

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	<b>Submitted Documents</b>
Application on Form-5/Form 5-D with required	Form5;
fee as per relevant SRO.	
Copy of DML (Renewal status) along with	Copy of DML provided
approval of relevant sections verified by	Approval of relevant section verified from letter No. F
licensing Division or inspection report for	2-13/95-Lic (Vol-IV) dated 19-07-2012
renewal of DML before 2005.	
GMP Status. Copy of Inspection report/GMP	GMP status verified from GMP certificate dated 04-
certificate.	08-2022.
Undertakings that the applied product is	Provided
exclusively for export purpose and the proposed	
names/ label/ colour do not resemble with	
already registered brands in importing country.	

Detail of the products is given below:

Bettin 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	Vial Packaging is not	Dy. No. 4862 (20.02.2023)	
	Solution for Injection	registered.	Rs.30, 000/- 02.02.2023)	
	Each multi-dose vial contains:		Rs. 45,000/- (24-04-2024)	

	Semaglutide4mg		
2.	Seglutide 2mg/1.5mL Solution for Injection Each multi-dose vial contains: Semaglutide2mg	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	Form5;	
fee as per relevant SRO.		
Copy of DML (Renewal status) along with	Copy of DML provided	
approval of relevant sections verified by	Approval of relevant section verified from Panel	
licensing Division or inspection report for	Inspection Report dated 01-03-2022	
renewal of DML before 2005.		
GMP Status. Copy of Inspection report/GMP	GMP status verified from GMP certificate dated 06-	
certificate.	07-2021.	
Undertakings that the applied product is	Provided	
exclusively for export purpose and the proposed		
names/ label/ colour do not resemble with		
already registered brands in importing country.		

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	Not Available	Dy. No. 17967 (17.07.2023)
	Solution for Injection in PFS		Rs.30, 000/- 0707.2023)
	Each 0.188mL contains:		Rs. 45,000/- (23-04-2024)
	Semaglutide0.25mg		
2.	Sematide 0.5mg Injection	Not Available	Dy. No. 17968 (17.07.2023)
	Solution for Injection in PFS		Rs.30, 000/- 0707.2023)
	Each 0.375mL contains:		Rs. 45,000/- (23-04-2024)
	Semaglutide0.5mg		
3.	Sematide 1mg Injection	Not Available	Dy. No. 17969 (17.07.2023)
	Solution for Injection in PFS		Rs.30, 000/- 0707.2023)
	Each 0.75mL contains:		Rs. 45,000/- (23-04-2024)
	Semaglutide1mg		

#### 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	<b>Submitted Documents</b>
Application on Form-5/Form 5-D with required	Form5;
fee as per relevant SRO.	
Copy of DML (Renewal status) along with	Copy of DML along with evidence of DML renewal
approval of relevant sections verified by	application is provided
licensing Division or inspection report for	Approval of relevant section verified from Licensing
renewal of DML before 2005.	Division Letter No. F. 3-6/2007-Lic (Vol-II) dated 25-
	10-2023.
GMP Status. Copy of Inspection report/GMP	New Section is approved on 25-10-2023
certificate.	
Undertakings that the applied product is	Provided
exclusively for export purpose and the proposed	
names/ label/ colour do not resemble with	
already registered brands in importing country.	

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	Rybelsus of Novo	Dy. No. 1703 (08.12.2023)
	Each uncoated tablet contains:	Nordisk	Rs.30, 000/- 15.11.2023)
	Semaglutide3mg		
2.	Semggo 7mg Tablet	Rybelsus of Novo	Dy. No. 1704 (08.12.2023)
	Each uncoated tablet contains:	Nordisk	Rs.30, 000/- 15.11.2023
	Semaglutide7mg		
3.	Semggo 14mg Tablet	Rybelsus of Novo	Dy. No. 1702 (08.12.2023)
	Each uncoated tablet contains:	Nordisk	Rs.30, 000/- 15.11.2023
	Semaglutide7mg		

#### 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	<b>Submitted Documents</b>
Application on Form-5/ Form 5-D with	Form5;
required fee as per relevant SRO.	
Copy of DML (Renewal status) along with	Copy of DML along with evidence of DML renewal
approval of relevant sections verified by	application is provided
licensing Division or inspection report for	Approval of relevant section of M/s Weather Folds
renewal of DML before 2005.	verified from Licensing Division Letter No. F. 3-
	6/2007-Lic (Vol-II) dated 25-10-2023.
GMP Status. Copy of Inspection report/GMP	New Section is approved on 25-10-2023
certificate.	
Undertakings that the applied product is	Provided
exclusively for export purpose and the	
proposed names/ label/ colour do not resemble	
with already registered brands in importing	
country.	

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	Rybelsus of Novo	Dy. No. 1701 (08.12.2023)
	Each uncoated tablet contains:	Nordisk	Rs.30, 000/- 15.11.2023)
	Semaglutide3mg		
2.	Maglu 7mg Tablet	Rybelsus of Novo	Dy. No. 1700 (08.12.2023)
	Each uncoated tablet contains:	Nordisk	Rs.30, 000/- 15.11.2023
	Semaglutide7mg		
3.	Maglu 7mg Tablet	Rybelsus of Novo	Dy. No. 1699 (08.12.2023)
	Each uncoated tablet contains:	Nordisk	Rs.30, 000/- 15.11.2023
	Semaglutide7mg		

#### 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	<b>Submitted Documents</b>
Application on Form-5/ Form 5-D with required fee as per	Form5;
relevant SRO.	

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	Clotenox 100mg of M/s	Dy. No.58 (02-01-2024)
	Solution for Injection	Nextar	Rs.30,000/- (07-01-2024)
	Each vial contains:		
	Enoxaparin Sodium100mg/1.0mL		
	(1000 IU of Anti-Xa activity)		
2.	Hepanox 8,000 IU/ 0.8mL	Enoxaparin sodium	Dy. No.59 (02-01-2024)
	Solution for Injection	PFS 8000IU/0.8mL by	Rs.30,000/- (07-01-2024)
	Each vial contains:	M/s Bio Medics	
	Enoxaparin Sodium80mg/0.8mL	Medical system	
	(8000IU of Anti-Xa activity)		
3.	Hepanox 6,000 IU/0.6mL	Enoxaparin sodium	Dy. No.55 (02-01-2024)
	Solution for Injection	PFS 6000IU/0.6mL by	Rs.30,000/- (07-01-2024)
	Each vial contains:	M/s Bio Medics	
	Enoxaparin Sodium60mg/0.6mL	Medical system	
	(6000IU of Anti-Xa activity)		
4.	Hepanox 4,000 IU/0.4mL	Enoxaparin sodium	Dy. No.56 (02-01-2024)
	Solution for Injection	PFS 4000IU/0.4mL by	Rs.30,000/- (07-01-2024)
	Each vial contains:	M/s Bio Medics	
	Enoxaparin Sodium40mg/0.4mL	Medical system	
	(4000IU of Anti-Xa activity)		
5.	Hepanox 2000 (20mg/0.2mL)	Enoxaparin sodium	Dy. No.57 (02-01-2024)
	Solution for Injection	PFS 2000IU/0.2mL by	Rs.30,000/- (07-01-2024)
	Each vial contains:	M/s Bio Medics	
	Enoxaparin Sodium20mg	Medical system	
	(2000 IU of Anti-Xa activity)		
Course			

#### 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	<b>Submitted Documents</b>
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of	Copy of DML provided
relevant sections verified by licensing Division or	The firm will import bulk labelled vials and
inspection report for renewal of DML before 2005.	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	Provided
export purpose and the proposed names/ label/ colour do	
not resemble with already registered brands in importing	
country.	

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	USFDA	Dy. No.7894 (20-03-2023)
	Solution for Injection in vials		Rs.75, 000/- (01-03-2023)
	Each vial contains:		
	Adalimumab40mg		

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°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 +	AFTODOLL-JEL Suspension for Injection	
	Strength	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
Finished product specifications	Saponin
Pharmacological Group	Biological Inactivated Viral Veterinary vaccine
Shelf life	18 months 2-8 °C
International availability	Not Submitted
Products already registered in	Foot and mouth Disease Vaccine manufactured by FGBI
Pakistan	Arriah Russia, Reg. No.052400, importer Mustafa Brothers
Type of Form, Dy. No. Date of	Form5-ADy. No.413 Date:23-01-2024 Fee Submitted:
Application, 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 country of 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.
TOTHURS OF DEAT	raditional 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 <u>Delegation of Functions:</u>

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,	M/s. Pharmix Laboratories (Pvt.)				
		C227, L111, L121, A210, A211,	Ltd., 21-Km Ferozpur Road,				
		A212, A230, B201	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	Diethylene Glycol	Not detected
				Chemicals,			
				Thailand.			
02	Glycerin	99.7%	000243IMD3C5L	M/s.	PT	Ethylene Glycol	Not detected
	USP			Musim	Mas	Diethylene Glycol	Not detected
				Indonesi	a	•	

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	M/s. Pharmix	L210	LHR-11-23-	EG content: 1.1116%
	120ml	Laboratories (Pvt.)		000038	DEG content:
		Ltd., Pakistan			0.1584%
02	-do-	-do-	B220	LHR-11-23-	EG content: 0.8874
				000026	%
					DEG content:
					0.1087%
03	-do-	-do-	H231	LHR-11-23-	EG content: 1.4282%
				000053	
04	-do-	-do-	C231	LHR-11-23-	EG content: 1.2158%
				000054	
05	-do-	-do-	J242	LHR-11-23-	EG content: 1.2366%
				000039	
06	-do-	-do-	D224	LHR-11-23-	EG content: 1.3484%
				000041	
07	-do-	-do-	G204	LHR-11-23-	EG content: 1.6828%
				000037	
08	Allergo Syrup 60ml	-do-	L210	LHR-11-23-	EG content: 1.4933%
				000040	
09	Mucorid syrup	-do-	C227	LHR-11-23-	EG content: 9.8709%
				000029	
10	-do-	-do-	B224	LHR-11-23-	EG content:
				000028	14.9891%
11	-do-	-do-	B201	LHR-11-23-	EG content:
				000030	17.5004%
12	-do-	-do-	C210	LHR-11-23-	EG content:
				000031	14.4483%
13	-do-	-do-	A210	LHR-11-23-	EG content:
				000047	12.7868%
14	-do-	-do-	B225	LHR-11-23-	EG content:
				000032	10.9240%
15	-do-	-do-	A230	LHR-11-23-	EG content:
				000033	12.0895%
16	Ulcofin syrup	-do-	B209	LHR-11-23-	Complies with
				000027	standard
17	-do-	-do-	L218	LHR-11-23-	Complies with
				000046	standard
18	Lorate suspension	-do-	J210	LHR-11-23-	EG content: 1.9558%
				000049	
19	Iropal syrup	-do-	H225	LHR-11-23-	EG content:
				000052	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 1/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 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:

- 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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