MINUTES OF 327th MEETING OF REGISTRATION BOARD HELD ON 13^{TH} APRIL, 2023

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Drug Regulatory Authority of Pakistan T.F. Complex, Mauve Area, G-9/4 Islamabad.

327th meeting of Registration Board was held on 13th April, 2023 in the Committee Room, Drug Regulatory Authority of Pakistan, G-9/4, 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.	Ch. Zeeshan Nazir Bajar, Additional Director (PE&R), DRAP.	Member/ Secretary
2.	Lt. Gen.(R) Prof. Dr. Karamat A. Karamat (HI-M.SI-M), Former	Co-opted Member
	Surgeon General Pakistan.	(Online)
3.	Maj. Gen. (R) Dr. Tahir Mukhtar Sayed, Inspector General (Hospitals),	Co-opted Member
	Fauji Foundation, Rawalpindi	(Online)
4.	Mr. Ajmal Sohail, Director (QA<), DRAP, Islamabad	Member
5.	Mr. Muhammad Aslam, Additional Draftsman, Ministry of law &	Member
	Justice, Islamabad.	(Online)
6.	Mr. Ghulam Mujtaba, Rep. of IPO, Islamabad	Member (Online)
7.	Dr. Imranullah Khan, Senior Drug Analyst, DTL, Govt. of KP, Peshawar	Member
8.	Dr. Ali Jan, Director, DTL, Govt. of Baluchistan	Member
9.	Dr. Asad Íbrar, Director DTL Govt. of Punjab, Bahawalpur	Member
10.	Syed Adnan Rizvi, Rep. of Director DTL. Govt. of Sindh. Karachi	Member (Online)
11.	Mr. Muhammad Kashif, Deputy Director, Representative of Biological	Member
	Evaluation & Research Division, DRAP	
12.	Mrs. Sadaf Ahmad, Assistant Director, Rep of MD&MC Division.	Member
13.	Dr. Qurban Ali, Veterinary Expert,	Coopted Member
		(Online)

Mr. Nadeem Alamgir (Pharma Bureau), Mr. Hamid Raza (Online) & Mr. Jalal Zafar (PPMA), Mr. Ziaulhaq & Mr. Amir (PCDA) attended the meeting as observers.

Item No. I 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. Muhammad 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.	Ms. Najia Saleem	Evaluator PEC-X
7.	Dr. Farhadullah	Evaluator PEC-XI
8.	Mr. Shahid Nawaz	Evaluator PEC-XIII
9.	Ms. Saima Hussain	Evaluator PEC-XV
10.	Ms. Sana Kanwal	Evaluator PEC-XX
11.	Mr. Tahir Waqas	Evaluator PEC-XXI
12.	Mr. Hafiz Sanaullah Babar	Evaluator PEC-XXII
13.	Ms. Maham Misbah	Evaluator PEC-XXIII
14.	Mr. Muneeb Ahmed Cheema	Deputy Director (PE&R)
15.	Mr. Ishtiaq	Ex AD PEC

Case no. 01 Registration applications of newly granted DML or New section (Human)

a. New DML

Name, address of Applicant / Marketing Authorization Holder	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 4 Km, Thokar Multan road, Lahore
Name, address of Manufacturing site.	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan 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)
Intended use of pharmaceutical product	☑ Do mestic sale☐ Export sale☐ Domestic and Export sales
Evidence of Manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-L Dated 29-04-2022 for sections of Injectable ampout (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
Dy. No. and date of submission	Dy.No 5899 dated 02-03-2023
Details of fee submitted	Rs.30,000/- dated 02-03-2023
The proposed proprietary name / brand name	Ezole 20mg Capsule
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Esomeprazole magnesium trihydrate enteric coat pellets eq. to Esomeprazole 20mg
Pharmaceutical form of applied drug	Capsule
Pharmacotherapeutic Group of (API)	PPI
Reference to Finished product specifications	USP
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Nexum 20 mg cap of M/s Getz pharma (Reg.# 033891)
GMP status of the Finished product manufacturer	Issuance of DML vide letter no. F.1-10/2019-L Dated 29-04-2022 for sections of Injectable amport (General), Capsule section (general), Dry powder vial section (general)
Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 2 23, Industrial Triangle, Kahuta Road, Islamaba Pakistan.

	Module III (Drug Substance)		Firm has submitted QOS template. Summarized nomenclature, structure, solubilities, physical description of manufacturi specifications, analytical verification, batch analys specification, reference states system and stability studied drug product is submitted.	information related to general properties, form, manufacturers, ing process and controls, procedures and its sis and justification of andard, container closure
			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		Both accelerated & long-te M/s Vision Pharma ha Esomeprazole EC pellets as	s been submitted for
	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.	
1			Pharmaceutical equivalence & CDP studies against the comparator product of "Nexum Capsules" in 0.1N HCl & PH 6.8 buffer dissolution mediums have been submitted with acceptable level of f2 results.	
	Analytical method validati	on/verification of product	Method validation studies h	nave been submitted.
		STABILITY ST	UDY DATA	
Manuf	Facturer of API	M/s Vision Pharmaceut Kahuta Road, Islamabad	ticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, d- Pakistan.	
API L	ot No.	EMZ046493		
	ption of Pack niner closure system)	Alu-Alu foil in unit carton		
, , ,		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time I	Time Period Real time: 6 months Accelerated: 6 months			
Freque	Frequency Accelerated: 0,3, 6 (Mor Real Time: 0, 3, 6 (Mor			
Batch	Batch No. Trial 01		Trial 02	Trial 03
Batch	Batch Size 1500 capsules		1500 capsules	1500 capsules
Manuf	Manufacturing Date 03-2022		03-2022	03-2022

No.	of Batches	03
	Administrativ	T
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML# SC 20160429 issued by NMPA valid till 18-10-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
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).	
2.	Name, address of Applicant / Marketing Authorization Holder	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore
	Name, address of Manufacturing site.	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan 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)
	Intended use of pharmaceutical product	☑ Domestic sale☐ Export sale☐ Domestic and Export sales
	Evidence of Manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Dy. No. and date of submission	Dy.No 5900 dated 02-03-2023
	Details of fee submitted	Rs.30,000/- dated 02-03-2023
	The proposed proprietary name / brand name	Ezole 40mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Esomeprazole magnesium trihydrate enteric coated pellets eq. to Esomeprazole 40mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Nexum 40 mg cap of M/s Getz pharma

GMP status of the Finished product manufacturer		Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
Name and address of AP	manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.
Module III (Drug Substance)		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.
		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		Both accelerated & long-term stability studies from M/s Vision Pharma has been submitted for Esomeprazole EC pellets as per Zone IVa conditions.
Module-III (Drug Produc	t):	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 equival dissolution profile	lence and comparative	Pharmaceutical equivalence & CDP studies against the comparator product of "Nexum Capsules" in 0.1N HCl & PH 6.8 buffer dissolution mediums have been submitted with acceptable level of f2 results.
Analytical method validation/verification of product STABILITY ST		Method validation studies have been submitted.
		UDY DATA
nufacturer of API M/s Vision Pharmaceut Kahuta Road, Islamabad		icals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, I- Pakistan.
I Lot No. EMZ046493		
scription of Pack ontainer closure system)	Alu-Alu foil in unit carte	on
Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
ne Period	Real time: 6 months	

		Accelerated: 6 months			
Frequency		Accelerated: 0,3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batcl	n No.	Trial 01	Trial 02	Trial 03	
Batcl	n Size	1500 capsules	1500 capsules	1500 capsules	
Man	ufacturing Date	03-2022	03-2022	03-2022	
No. o	of Batches		03		
		Administrativ	e 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.		Submitted		
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Submitted		
4.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			itted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.		N/A	A	
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).			itted	

Remarks of Evaluator:

Section#	Observations	Firm's response
3.2. S.4.1	Drug Substance Specifications, Analytical Procedure & Analytical Method Verification Studies Shall Be Submitted from M/s May & Baker.	Firm has submitted drug Substance Specifications, Analytical Procedure & Analytical Method Verification Studies from M/s May & Baker.
3.2.S.4.4	COA of relevant batch of API from drug substance manufacturer shall be submitted used for manufacturing of drug product trial batches.	Submitted.
3.2.P.5	Clarification shall be submitted that which test of Dissolution has been applied from the USP monograph of "Esomeprazole Magnesium Delayed-Release Capsules"	Firm has referred to USP Dissolution Test 1 from the USP monograph of "Esomeprazole Magnesium Delayed-Release Capsules"
3.2.P.5.3	 Performance of specificity parameter shall be submitted in analytical method verification studies. Concentrations in terms of mg/ml shall be submitted for the performance of accuracy parameter. 	Performance of specificity parameter gas been submitted. Concentrations in terms of mg/ml for the performance of accuracy parameter has been submitted.
3.2.P.8	 Complete batch manufacturing record of three stability batches shall be submitted. Raw data sheets for the performance of dissolution test during stability studies shall be submitted. 	Submitted.

Decision: Registration Board approved the applications of Ezole 40mg Capsule & Ezole 20mg 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.

3.	Name, address of Applicant / Marketing Authorization Holder	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore
	Name, address of Manufacturing site.	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan 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)
	Intended use of pharmaceutical product	☑ Domestic sale☐ Export sale☐ Domestic and Export sales
	Evidence of Manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Dy. No. and date of submission	Dy.No 5901 dated 02-03-2023
	Details of fee submitted	Rs.30,000/- dated 02-03-2023
	The proposed proprietary name / brand name	Ezole 40mg Dry powder Vial
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Esomeprazole Sodium Eq. to Esomeprazole40mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Acireg of Barret hodgson Pakistan
	GMP status of the Finished product manufacturer	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.

		Firm has submitted QOS	_
		template. Summarized nomenclature, structure, solubilities, physical description of manufacturi specifications, analytical verification, batch analys specification, reference states system and stability studied drug product is submitted.	general properties, form, manufacturers, ng process and controls, procedures and its sis and justification of undard, container closure
		The firm as submitted structure, general properti form, manufacturers, descriptoress and controls, substance.	es, solubilities, physical ription of manufacturing pecifications, analytical ation, batch analysis and ion, reference standard,
Stability studies		Both accelerated & long-te M/s Vision Pharma ha Esomeprazole EC pellets as	s been submitted for
Module-III (Drug Product):		The firm has submitted description of manufacturi impurities, specifications, its verification studies, justification of specification container closure system an product.	ng process and controls, analytical procedure and batch analysis and ion, reference standard,
Pharmaceutical equivaled dissolution profile	•		alence against the 'Nexum Injection' has
Analytical method validati	on/verification of product	Method validation studies h	ave been submitted.
	STABILITY ST	UDY DATA	
Manufacturer of API	Kahuta Road, Islamabad	icals (Pvt.) Ltd, Plot No. 22 I-Pakistan.	2-23, Industrial Triangle,
API Lot No.	2112901		
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 (Mo			
Batch No. Trial 01		Trial 02	Trial 03
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	03-2022	03-2022	03-2022
No. of Batches		03	
	Administrativ	e 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.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
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.S.4.4	COA of relevant batch of API from drug substance manufacturer shall be submitted, used for manufacturing of drug product trial batches.	Submitted.
3.2.P.2.6	Compatibility studies with the diluent shall be submitted.	Submitted.
3.2.P.5	 Justification shall be submitted for the specifications of "filled weight per vial." Analytical procedure for the drug product testing shall be submitted. 	 Firm has justified the filled weight per unit vial against the potency of drug substance determined during drug substance analysis. Submitted.
3.2.P.8	Complete batch manufacturing record of three stability batches shall be submitted.	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.

Case no. 02 Registration applications of Form 5F (Human)

4.	Name, address of Applicant / Marketing Authorization Holder	M/s Islam Pharmaceutical, 7Km Pasrur Road Sialkot, Islamabad from M/s Bio-Labs (Pvt) Ltd	
	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) 	
	Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☐ Domestic sale	

	□ Export sale☑ Domestic and Export sales		
Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.		
Dy. No. and date of submission	Dy. No 6961 dated 02-03-2021		
Details of fee submitted	Rs.50,000/- dated 18-01-2021		
The proposed proprietary name / brand name	Celine Injection 500mg IM		
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium eq. to Ceftriaxone 500mg		
Pharmaceutical form of applied drug	Sterile powder for injection		
Pharmacotherapeutic Group of (API)	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals		
GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.		
Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd First medical zone, economic and technological development zone, datong, China.		
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties solubilities, physical form, manufacturers, Characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard container closure system and stability studies of drust substance. The firm has summarized information of drug product including it description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocol control of excipients, control of drug product specifications, analytical procedure validation/verification of analytical procedure batch analysis, justification of specification reference standard or materials, container closure system and stability.		
Module III (Drug Substance)	Firm has submitted detailed data for both drusubstance data related to nomenclature, structur general properties, solubilities, physical formanufacturers, description of manufacturing proce and controls, specifications, analytical procedurand its validation, batch analysis and justification specification, reference standard, container closur system and stability studies of drug substance.		

	Module-III (Drug Product):		Firm has submitted stability study 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 36 months. (Batch No. 011302001, 011302002, 011302003) 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 cordissolution profile	mparative		has performed pharma the product Rocephin 5	
	Analytical method validation/v product	erification of		d verification studieng linearity, range, city.	
	ST	ABILITY STU	JDY DA	ATA	
Manufa	acturer of API			qida Pharmaceuticals C chnological developmer	
API Lo	t No.	2081704066			
	otion of Pack iner closure system)	Glass vial			
Stabilit	y Storage Condition		$C \pm 2^{\circ}C / 65\% \pm 5\% RH$ $0^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\% RH$		
Time P	eriod	Real time: 24 r Accelerated: 6			
Freque	ncy		, 3, 6 (Months) 3, 6, 9, 12, 18 & 24 (Months)		
Batch N	No.	VP-1436		VP-1462	VP-1319
Batch S	Size	40,000 Vials		40,000 Vials	40,000 Vials
Manufa	acturing Date	01-2018		02-2018	04-2018
No. of	Batches			03	
		Administrative	e Portion		
1.	Reference of previous approval of apstability study data of the firm (if ar	. *	Not sul	omitted	
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 commercial invoice (invoice#W200910) approved by AD DRAP I&E Islamabad dated 07-07-2020 for the import of Ceftriaxone sodium from M/s Sinopharm Weiqida Pharmaceuticals Co Ltd.		by AD DRAP I&E for the import of
4	Data of stability batches will be attested respective documents like of Raw data sheets, COA, summary data	chromatograms,			

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

- The batch no. declared in the stability summary sheets are different from those declared in section 3.2. P.5.4.
- Same stability data has been submitted for the 500mg IV instead of 500mgIM.

Firm has submitted revised stability data for new batches detailed as under:

Batch number	Mfg. date	Exp. Date	Date of initiation	Batch size
VP-299	10-2019	10-2021	30-10-2019	33,333 vials
VP-300	10-2019	10-2021	30-10-2019	33,333 vials
VP-301	10-2019	10-2021	30-10-2019	33,333 vials

- Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted 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 Islam Pharmaceutical, 7Km Pasrur Road Sialkot, Islamabad from M/s Bio-Labs (Pvt) Ltd	
	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) 	
	Status of application	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	□ Domestic sale□ Export sale☑ Domestic and Export sales	
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.	
	Dy. No. and date of submission	Dy. No 7164 dated 04-03-2021	
	Details of fee submitted	Rs.50,000/- dated 18-01-2021	
	The proposed proprietary name / brand name	Celine Injection 1g IM	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium eq. to Ceftriaxone 1gm	
	Pharmaceutical form of applied drug	Sterile powder for injection	
	Pharmacotherapeutic Group of (API)	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals
GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.
Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Lt First medical zone, economic and technologic development zone, datong, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related nomenclature, structure, general properties solubilities, physical form, manufacturers, Characterization, specifications, analytic procedures and its validation, batch analysis are justification of specification, reference standar container closure system and stability studies of drust substance. The firm has summarized information of drug product including indescription, composition, pharmaceutic development, manufacture, manufacturing procedure and process control, process validation protocol control of excipients, control of drug product specifications, analytical procedure validation/verification of analytical procedure batch analysis, justification of specification reference standard or materials, container closure system and stability.
Module III (Drug Substance)	Firm has submitted detailed data for both dri substance data related to nomenclature, structur general properties, solubilities, physical for manufacturers, description of manufacturing proceand controls, specifications, analytical procedur and its validation, batch analysis and justification specification, reference standard, container closus system and stability studies of drug substance.
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 $40^{\circ} \pm 2^{\circ}$ C $/75\% \pm 5\%$ RH for months. The real time stability data is conducted 30° C $\pm 2^{\circ}$ C $/65\% \pm 5\%$ RH for 36 months. (Batch No. 011302001, 011302002, 011302003)
Module-III (Drug Product):	The firm has submitted detail of manufactured description of manufacturing process and control impurities, specifications, analytical procedure at its verification studies, batch analysis at justification of specification, reference standar container closure system and stability studies of draproduct.
Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalen against the product Rocephin 1gm IM injection.

	Analytical method valid product	lation/verification of	Metho includi specifi	ng linearity, ran	tudies have submitted ge, accuracy, precision,
		STABILITY STU	JDY DA	TA	
Manuf	Facturer of API	M/s. Sinopharm Wei economic and technol	•		Ltd, First medical zone, datong, China
API L	ot No.	2081704052			
	ption of Pack niner closure system)	Glass 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: 24 months Accelerated: 6 months	S		
Freque	ency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch	No.	VP-1613		VP-1560	VP-1457
Batch	Size	40,000 Vials		40,000 Vials	40,000 Vials
Manuf	facturing Date	07-2018		05-2018	02-2018
No. of	Batches		03		
		Administrative	e Portio	n	
1.	Reference of previous approv stability study data of the fir		Not su	omitted	
2.			GMP certificate (Certificate# SX20180229) of M/s Sinopharm Weiqida Pharmaceuticals Co Ltd. issued by Shangxi Food & Drug Administration, valid up to 05-06-2023.		
3.	. Documents for the procurement of API with approval from DRAP (in case of import).		h Firm has submitted copy of commercial invoice (invoice#W200910) approved by AD DRAP I&I Islamabad dated 07-07-2020 for the import of Ceftriaxone sodium from M/s Sinopharm Weiqida Pharmaceuticals Co Ltd.		
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		Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		

- The batch no. declared in the stability summary sheets are different from those declared in section 3.2. P.5.4.
- Same stability data has been submitted for the 1gm IV and 1gm IM application.

Firm has submitted revised stability data for new batches detailed as under:

Batch number	Mfg. date	Exp. Date	Date of initiation	Batch size
VP-173	07-2019	07-2021	28-07-2019	33,333 vials
VP-174	07-2019	07-2021	28-07-2019	33,333 vials
VP-175	07-2019	07-2021	28-07-2019	33,333 vials

- Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted 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 Bio-Next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat
	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)
	Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	□ Domestic sale□ Export sale☑ Domestic and Export sales
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
	Dy. No. and date of submission	Dy.No 6959 dated 02-03-2021
	Details of fee submitted	Rs.50,000/- dated 23-04-2020
	The proposed proprietary name / brand name	Nextone Injection 1g IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium eq. to Ceftriaxone 1gm
	Pharmaceutical form of applied drug	Sterile powder for injection
	Pharmacotherapeutic Group of (API)	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals
	GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.
	Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		substa	ner closure system and st nce. The firm has summ	arized	
		description development develo	ation of drug proption, composition pment, manufacture, mocess control, process of excipients, control analytic ion/verification of an analysis, justification and stability.	pharmaceutical nanufacturing process validation protocols, ol of drug product, cal procedures, nalytical procedures, n of specifications,	
Module III (Drug Substance)	substant general manufication and co- and its specifi	has submitted detailed nee data related to nor l properties, solubility acturers, description of rontrols, specifications, validation, batch analyst cation, reference standar and stability studies of	menclature, structure, ties, physical form, nanufacturing process analytical procedures sis and justification of ard, container closure	
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 $^{\rm O}$ \pm 2 $^{\rm O}$ C /75% \pm 5% RH for 6 months. The real time stability data is conducted at $30^{\rm O}$ C \pm 2 $^{\rm O}$ C / 65% \pm 5% RH for 36 months. (Batch No. 011302001, 011302002, 011302003)			
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 dissolution profile	and comparative	Firm has performed pharmaceutical equivalence against the product Rocephin 1gm IM injection.			
Analytical method valid product		Method verification studies have submitted including linearity, range, accuracy, precision, specificity.			
	STABILITY STU	J DY D A	ATA		
Manufacturer of API	economic and technol	iqida Pharmaceuticals Co Ltd, First medical zone, logical development zone, datong, China			
API Lot No.	2081704052				
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: 24 months Accelerated: 6 month		s			
Frequency	Accelerated: 0, 3, 6 (N) Real Time: 0, 3, 6, 9,				
Batch No.	VP-1613		VP-1560	VP-1457	

Batch Size		40,000 Vials		40,000 Vials	40,000 Vials
Manufacturing Date 07-2018		07-2018		05-2018	02-2018
No. of	Batches			03	
		Administrative	Portio	n	
1.	Reference of previous approv stability study data of the firm		Not submitted		
2.			GMP certificate (Certificate# SX20180229) of M/s Sinopharm Weiqida Pharmaceuticals Co Ltd. issued by Shangxi Food & Drug Administration, valid up to 05-06-2023.		
3.	B. Documents for the procurement of API with approval from DRAP (in case of import).		Firm has submitted copy of commercial invoice (invoice#W200910) approved by AD DRAP I&E Islamabad dated 07-07-2020 for the import of Ceftriaxone sodium from M/s Sinopharm Weiqida Pharmaceuticals Co Ltd.		
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		Not sul	omitted	
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).		temper		monitoring of real time

Remarks: The applied product to be manufactured by M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad have 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 Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2- Pharma Zone	
	Lahore, Sharikpur Road, Sheikhupura	
Manufacturer firm	M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road,	
	Islamabad	
Brand Name	CEFEXO 1g Injection IV	
Batch No. of drug product	VP-1457,VP-1560,VP-1613	
Case No.	750	
RB meeting	316	

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.

7.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat	
	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) 	
	Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)	

Intended use of pharmaceutical product	☐ Domestic sale
	☐ Export sale
	□ Domestic and Export sales
Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
Dy. No. and date of submission	Dy.No 7098 dated 03-03-2021
Details of fee submitted	Rs.50,000/- dated 23-04-2020
The proposed proprietary name / brand name	Nextone Injection 250mg IM
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium Eq. to Ceftriaxone 250mg
Pharmaceutical form of applied drug	Sterile powder for injection
Pharmacotherapeutic Group of (API)	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals 025876
GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.
Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, 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 specifications, reference standard or materials, container closure system and stability.
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, 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 stability study 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 36 months. (Batch No. 011302001, 011302002, 011302003) 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 dissolution profile	e and comparative	agains		narmaceutical equivalence 250mg Injection of M/s	
	Analytical method valid product	dation/verification of			es have submitted including precision, specificity.	
		STABILITY ST	TUDY I	DATA		
Manufa	acturer of API			eiqida Pharmaceuticals Co Ltd, First medical zone, logical development zone, datong, China		
API Lo	ot No.	2081704061				
	otion of Pack iner closure system)	Glass vial				
Stabilit	y Storage Condition	Real time: 30°C ± 2°C Accelerated: 40°C ± 2				
Time P	Period	Real time: 24 months Accelerated: 6 month				
Freque	ncy	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6, 9,				
Batch l	No.	VP-1522		VP-1523	VP-1660	
Batch S	Size	40,000 Vials		40,000 Vials	40,000 Vials	
Manufa	acturing Date	04-2018		05-2018	08-2018	
Date of	f Initiation	05-05-2018		04-06-2018	19-09-2018	
No. of	Batches		03			
		Administrati	ve Port	ion		
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.		GMP certificate (Certificate# SX20180229) of M/s Sinopharm Weiqida Pharmaceuticals Co Ltd. issued by Shangxi Food & Drug Administration, valid up to 05-06-2023.		naceuticals Co Ltd. issued	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		(invoid Islama Ceftria	e#W200910) approbad dated 07-07-	y of commercial invoice oved by AD DRAP I&E 2020 for the import of M/s Sinopharm Weiqida	

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 data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks: The applied product to be manufactured by M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad have 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 Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2- Pharma Zone
	Lahore, Sharikpur Road, Sheikhupura
Manufacturer firm	M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road,
	Islamabad
Brand Name	CEFEXO 250mg Injection IM
Batch No. of drug product	VP-1522,VP-1523,VP-1660
Case No.	748
RB meeting	316

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.

8.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat
	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)
	Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	□ Domestic sale□ Export sale☑ Domestic and Export sales
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
	Dy. No. and date of submission	Dy.No 6958 dated 02-03-2021
	Details of fee submitted	Rs.50,000/- dated 23-04-2020
	The proposed proprietary name / brand name	Nextone Injection 500mg IM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium eq. to Ceftriaxone 500mg
	Pharmaceutical form of applied drug	Sterile powder for injection
	Pharmacotherapeutic Group of (API)	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals
GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.
Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Lt First medical zone, economic and technologic development zone, datong, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related nomenclature, structure, general properties solubilities, physical form, manufacturers, Characterization, specifications, analytic procedures and its validation, batch analysis are justification of specification, reference standar container closure system and stability studies of drus substance. The firm has summarized information of drug product including it description, composition, pharmaceutic development, manufacture, manufacturing procedure and process control, process validation protocol control of excipients, control of drug product specifications, analytical procedure validation/verification of analytical procedure batch analysis, justification of specification reference standard or materials, container closu system and stability.
Module III (Drug Substance)	Firm has submitted detailed data for both dra substance data related to nomenclature, structure general properties, solubilities, physical for manufacturers, description of manufacturing procedure and controls, specifications, analytical procedure and its validation, 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 batch of drug substance at both accelerated as well as retime conditions. The accelerated stability data conducted at 40 $^{\rm O}$ \pm 2 $^{\rm O}$ C /75% \pm 5% RH for months. The real time stability data is conducted $30^{\rm O}$ C \pm 2 $^{\rm O}$ C / 65% \pm 5% RH for 36 months. (Batch No. 011302001, 011302002, 011302003)
Module-III (Drug Product):	The firm has submitted detail of manufactured description of manufacturing process and control impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standar container closure system and stability studies of draproduct.
Pharmaceutical equivalence and comparative	Firm has performed pharmaceutical equivalen

	dissolution profile		against	the product Rocephin 5	500mg injection.
	product		Method verification studies have submitted including linearity, range, accuracy, precision, specificity.		
	ST	CABILITY STU	JDY DA	ATA	
Manufa	acturer of API			qida Pharmaceuticals C chnological developmer	
API Lo	ot No.	2081704066			
	otion of Pack iner closure system)	Glass vial			
Stabilit	y Storage Condition			/ 65% ± 5%RH C / 75% ± 5%RH	
Time P	Period	Real time: 24 r Accelerated: 6			
Freque	ncy	Accelerated: 0 Real Time: 0, 3		Ionths) 2, 18 & 24 (Months)	
Batch I	No.	VP-1436		VP-1462	VP-1319
Batch S	Size	40,000 Vials		40,000 Vials	40,000 Vials
Manufa	acturing Date	01-2018		02-2018	04-2018
No. of	Batches		03		
		Administrative	e Portio	n	
1.	Reference of previous approval of apstability study data of the firm (if ar		Not submitted		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Sinoph	arm Weiqida Pharmace ngxi Food & Drug Adm	uticals Co Ltd. issued
3.	3. Documents for the procurement of API with approval from DRAP (in case of import).		(invoic Islamal Ceftria	nas submitted copy of e#W200910) approved bad dated 07-07-2020 xone sodium from M/s aceuticals Co Ltd.	by AD DRAP I&E for the import of
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 sul	omitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).		temper	has submitted record ature and humidity mo celerated stability chaml	onitoring of real time

- The batch no. declared in the stability summary sheets are different from those declared in section 3.2. P.5.4.
- Same stability data has been submitted for the 500mg IV instead of 500mgIM.

Firm has submitted revised stability data for new batches detailed as under:

Batch number	Mfg. date	Exp. Date	Date of initiation	Batch size
VP-299	10-2019	10-2021	30-10-2019	33,333 vials
VP-300	10-2019	10-2021	30-10-2019	33,333 vials
VP-301	10-2019	10-2021	30-10-2019	33,333 vials

- Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the 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 Davis Pharmaceuticals Laboratories. Plot No. 121, 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)
Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
Intended use of pharmaceutical product	□ Domestic sale□ Export sale☑ Domestic and Export sales
Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
Dy. No. and date of submission	Dy.No 7096 dated 03-03-2021
Details of fee submitted	Rs.50,000/- dated 28-12-2020
The proposed proprietary name / brand name	Ceftione 500mg IM Injection
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium eq. to Ceftriaxone 500mg
Pharmaceutical form of applied drug	Sterile powder for injection
Pharmacotherapeutic Group of (API)	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals
GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.

Name and address of API manufact	urer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China.		
Module-II (Quality Overall Summa	ry)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, 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 both 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		Firm has submitted stability study 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 36 months. (Batch No. 011302001, 011302002, 011302003)		
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 cordissolution profile	mparative	Firm has performed pharmaceutical equivalence against the product Rocephin 500mg injection.		
Analytical method validation/v product	erification of	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.		
	ABILITY STU	JDY DATA		
Manufacturer of API		m Weiqida Pharmaceuticals Co Ltd, First medical c and technological development zone, datong, China		
API Lot No.	2081704066			

	Description of Pack (Container closure system) Glass vial				
Stability Storage Condition Real time: 30°C		$C \pm 2^{\circ}C / 65\% \pm 5\%RH$ $0^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%RH$			
Time I	Period	Real time: 24 1 Accelerated: 6			
Freque	ency	Accelerated: 0 Real Time: 0,		Months) 12, 18 & 24 (Month	s)
Batch	No.	VP-1436		VP-1462	VP-1319
Batch	Size	40,000 Vials		40,000 Vials	40,000 Vials
Manuf	Cacturing Date	01-2018		02-2018	04-2018
No. of	Batches			03	
		Administrative	Portio	n	
1.	1. Reference of previous approval of applications with stability study data of the firm (if any)		Not su	bmitted	
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		GMP certificate (Certificate# SX20180229) of M/s Sinopharm Weiqida Pharmaceuticals Co Ltd. issued by Shangxi Food & Drug Administration, valid up to 05-06-2023.		
3. Documents for the procurement of API with approval from DRAP (in case of import).		(invoic Islama Ceftria	e#W200910) approbad dated 07-07-2	y of commercial invoice oved by AD DRAP I&E 2020 for the import of M/s Sinopharm Weiqida	
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		Not su	bmitted	
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real		temper		monitoring of real time

- The batch no. declared in the stability summary sheets are different from those declared in section 3.2. P.5.4.
- Same stability data has been submitted for the 500mg IV instead of 500mgIM.

Firm has submitted revised stability data for new batches detailed as under:

Batch number	Mfg. date	Exp. Date	Date of initiation	Batch size
VP-299	10-2019	10-2021	30-10-2019	33,333 vials
VP-300	10-2019	10-2021	30-10-2019	33,333 vials
VP-301	10-2019	10-2021	30-10-2019	33,333 vials

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

Authorization Holder	Plot No. 121, 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)
Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
Intended use of pharmaceutical product	□ Domestic sale□ Export sale☑ Domestic and Export sales
Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
Dy. No. and date of submission	Dy.No 7103 dated 03-03-2021
Details of fee submitted	Rs.50,000/- dated 28-12-2020
The proposed proprietary name / brand name	Ceftione Injection 1g IM
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium eq. to Ceftriaxone 1gm
Pharmaceutical form of applied drug	Sterile powder for injection
Pharmacotherapeutic Group of (API)	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals
GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.
Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, 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,

		batch referen	analysis, justification	analytical procedures, on of specifications, rials, container closure
Module III (Drug Substance)		substar general manufa and co and its specific	nce data related to not properties, solubil acturers, description of ontrols, specifications, validation, batch anal	ed data for both drug omenclature, structure, lities, physical form, f manufacturing process , analytical procedures ysis and justification of dard, container closure of drug substance.
Stability studies		of drug time c conduc months 30°C ±	g substance at both accorditions. The accelerated at $40^{\circ} \pm 2^{\circ}$ C	
Module-III (Drug Product):		The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.		
Pharmaceutical equivalence dissolution profile	and comparative	Firm has performed pharmaceutical equivalence against the product Rocephin 1gm IM injection.		
Analytical method validation/verification of product		Method verification studies have submitted including linearity, range, accuracy, precision, specificity.		
	STABILITY STU	J DY DA	TA	
Manufacturer of API	M/s. Sinopharm Wei economic and technol			d, First medical zone, ong, China
API Lot No.	2081704052			
Description of Pack (Container closure system)	Glass vial			
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2$			
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. VP-1613			VP-1560	VP-1457
Batch Size	Batch Size 40,000 Vials		40,000 Vials	40,000 Vials
Manufacturing Date	07-2018		05-2018	02-2018
No. of Batches			03	·
	Administrative	e Portio	n	
Reference of previous approvious stability study data of the firm		Not sul	bmitted	

2.	* *	GMP certificate (Certificate# SX20180229) of M/s Sinopharm Weiqida Pharmaceuticals Co Ltd. issued by Shangxi Food & Drug Administration, valid up to 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice#W200910) approved by AD DRAP I&E Islamabad dated 07-07-2020 for the import of Ceftriaxone sodium from M/s Sinopharm Weiqida Pharmaceuticals Co Ltd.
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 data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

- The batch no. declared in the stability summary sheets are different from those declared in section 3.2. P.5.4.
- Same stability data has been submitted for the 1gm IV instead of 1gm IM application.

Firm has submitted revised stability data detailed as under:

Batch number	Mfg. date	Exp. Date	Date of initiation	Batch size
VP-173	07-2019	07-2021	28-07-2019	33,333 vials
VP-174	07-2019	07-2021	28-07-2019	33,333 vials
VP-175	07-2019	07-2021	28-07-2019	33,333 vials

- Manufacturer will place first three production batches on long term stability studies throughout
 proposed shelf life and on accelerated studies for six months as per the 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.	Name, address of Applicant / Marketing Authorization Holder	M/s Davis Pharmaceuticals Laboratories. Plot No. 121, 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)
	Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	□ Domestic sale□ Export sale☑ Domestic and Export sales
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-02-2011 which specifies Dry Powder Injection (Cephalosporin) for M/s Bio labs.
	Dy. No. and date of submission	Dy.No 7102 dated 03-03-2021

Details of fee submitted	Rs.50,000/- dated 28-12-2020
The proposed proprietary name / brand name	Ceftione Injection 250mg IV
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium Eq. to Ceftriaxone 250mg
Pharmaceutical form of applied drug	Sterile powder for injection
Pharmacotherapeutic Group of (API)	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)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals 025876
GMP status of the Finished product manufacturer	GMP certificate is valid upto 03-07-2022.
Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceuticals Co Ltd, First medical zone, economic and technological development zone, datong, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, 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 both 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	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 $^{\rm o}$ \pm 2 $^{\rm o}$ C /75% \pm 5% RH for 6 months. The real time stability data is conducted at $30^{\rm o}$ C \pm 2 $^{\rm o}$ C / 65% \pm 5% RH for 36 months. (Batch No. 011302001, 011302002, 011302003)

	Module-III (Drug Product):		descrip impuri its ve justific	otion of manufactur ties, specifications, erification studies eation of specification ner closure system as	detail of manufacturers, ring process and controls, analytical procedure and , batch analysis and tion, reference standard, nd stability studies of drug	
	Pharmaceutical equivalence dissolution profile	and comparative	agains	Firm has performed pharmaceutical equivalence against the product Tuff 250mg IV Injection of M/s Healthtek (Pvt.) Ltd.		
	Analytical method valid product	ation/verification of	Metho includi specifi	ing linearity, rang	tudies have submitted ge, accuracy, precision,	
		STABILITY STU	J DY D A	ATA		
Manufa	cturer of API	M/s. Sinopharm Wei economic and technol			Ltd, First medical zone, latong, China	
API Lot	No.	2081704061				
	tion of Pack ner closure system)	Glass vial				
Stability	Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2$				
Time Pe	eriod	Real time: 24 months Accelerated: 6 months	S			
Frequen	су	Accelerated: 0, 3, 6 (N) Real Time: 0, 3, 6, 9,				
Batch N	lo.	VP-1522		VP-1523	VP-1660	
Batch S	ize	40,000 Vials		40,000 Vials	40,000 Vials	
Manufa	cturing Date	04-2018		05-2018	08-2018	
Date of	Initiation	05-05-2018		04-06-2018	19-09-2018	
No. of E	Batches			03		
		Administrative	e Portio	n		
	Reference of previous approves tability study data of the firm	* *	Not su	bmitted		
	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Sinoph	arm Weiqida Pharm ngxi Food & Drug A	ate# SX20180229) of M/s naceuticals Co Ltd. issued Administration, valid up to	
	3. Documents for the procurement of API with approval from DRAP (in case of import).		(invoic Islama Ceftria	ce#W200910) approbad dated 07-07-2	y of commercial invoice oved by AD DRAP I&E 2020 for the import of M/s Sinopharm Weiqida	
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.					
	Compliance Record of HPL audit trail reports on product		Not su	bmitted		

6. humidity monitoring of stability chambers (real time and accelerated).

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

Remarks of Evaluator:

Section#	Observations	Firm's response
3.2.S.4	 Justification shall be submitted regarding drug substance specifications & analytical procedure proposed by the drug substance manufacturer, whether it is as per USP or Chinese pharmacopoeia. Assay limits proposed in the drug substance specifications proposed by the drug substance manufacturer are not as per USP monograph for "Ceftriaxone sodium". Copy of drug substance specifications and analytical procedure applied by Drug product manufacturer shall be submitted. Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. 	 Firm has declared drug substance specifications as per USP. Firm has submitted revised specifications from drug substance manufacturer i.e., M/s Sinopharm Weiqid: Pharmaceuticals Co Ltd., with Assay limits as per USP. Analytical method verification studies report has been submitted.
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.	 Firm has submitted that the Assay results are for the Ceftriaxone base only. Firm has submitted that the Assay results are for the Ceftriaxone base only. COA of drug substance submitted from M/s Bio Lab & M/s Sinopharm
3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided	Firm has submitted COA of working standard from M/s Bio-labs
3.2.P.2.2.1	Test of water determination has not been performed in "Pharmaceutical equivalence" studies.	Firm has submitted revised Pharmaceutical equivalence studies wherein test of water determination has been added.
3.2.P.2.6	Compatibility study with the reconstitution diluent shall be submitted.	Submitted.
3.2.P.5.1	Submit the document of Drug product specifications and Drug product testing method in use by M/s Bio-Labs.	Firm has submitted analytica procedure as per USI monograph.
3.2.P.6	Submit readable copy of COA of primary / secondary reference standard applied for the analysis during stability studies.	Firm has submitted COA of working standard from M/s Bio-labs
3.2.P.8	 Documents for the procurement of API with approval from DRAP for the relevant batch# of drug substance which has beenused to formulate stability batches. Submit raw data sheets for stability studies, reflecting the details of Standard weight, Sample dilution preparation, Potency of Reference standard and Calculation formula applied for the Assay test. Complete Batch Manufacturing Records of drug product stability batches shall be submitted. 	• Firm has submitted copy of commercial invoice specifying import of 1200Kg Ceftriaxone sodium (sterile) from Sinopharm dated 22-12 2017. The invoice specifies multiple batches of Ceftriaxone. In which the quantity of lot No. Q011711032 is 250kg. Firm has submitted raw data sheets and stability summary sheets, wherein previously test of sterility particulate matter and water

				content has been included in previously submitted sheets. • BMRs have been submitted.
substa of reg • M pr re • M	ance specification distration letter. Ianufacturer will roposed shelf life egistration applic	place first three production bat and on accelerated studies for s ation. perform process validation of f	/2012-B&A/ tches on lon six months a	correction/pre-approval change in drug DRAP dated 07-05-2021, before issuance g term stability studies throughout s per the commitment submitted in the atches as per the commitment submitted
12.	Name, address o Authorization He	f Applicant / Marketing older		n Pharma Private Limited Industrial Estate, Sundar Raiwind ore
	Name, address o	f Manufacturing site.		Pharma Private Limited rangi creek road Karachi
	Status of the app	licant	☐ Manufac ☐ Importer ☑ Is involv	
	Status of applica	tion		ng Product (NDP) Drug Product (GDP)

Authorization Holder	Road, Lahore Estate, Sundar Raiwind		
Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi		
Status of the applicant	 ☐ Manufacturer ☐ Importer ☑ Is involved in none of the above (contract giver) 		
Status of application	✓ New Drug Product (NDP)☐ Generic Drug Product (GDP)		
Intended use of pharmaceutical product	□ Domestic sale□ Export sale☑ Domestic and Export sales		
Dy. No. and date of submission	Dy.No 672 dated 07-01-2022		
Details of fee submitted	Rs.75,000/- dated 25-11-2021		
The proposed proprietary name / brand name	Dapazin 10mg Tablet		
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin10mg		
Pharmaceutical form of applied drug	Oblong, Dark Red color, Biconvex, film coated tablet, plain from both sides		
Pharmacotherapeutic Group of (API)	Anti-Diabetic		
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	Farxiga tablet of USFDA approved		

For generic drugs (me-too status)	Dapaglu 10mg tablet of M/s Scotmann		
GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Tablet section (General & Psycotropic) app	proved.	
Name and address of API manufacturer.	M/s Jiangsu Yogan Pharmaceutical Co., Ltd, China		
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO template. Summarized information nomenclature, structure, general solubilities, physical form, manufacturers, of manufacturing process and controls, specifications, analytical procedures verification, batch analysis and justi specification, reference standard, contain system and stability studies of drug substant product is submitted.	related to properties description impurities and its fication of ner closure	
Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance		
Stability studies	The firm has submitted copy of accelerated, 06 Months $(40^{\circ}\text{C} \pm 2^{\circ}\text{C} \& 75\pm5\%\text{RH}) \& \text{long term, 06 Months}$ $(30^{\circ}\text{C} \pm 2^{\circ}\text{C} \& 65\pm5\%\text{RH})$ stability study reports of 03 batches.		
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.		
Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Comparative dissolution their product (Flucid Tablets) with Innovat "Forxiga Tablets" The details are as follow	or's Brand	
	Feature Reference. Product Genix Brand Name Forxiga 10mg Flucid	t	
	Tablet Batch No. AAP0252 19SB-2 Mfg. Date 10/2016 01-2019 Exp. Date 09/2019 01-202	9	
	Comparative dissolution studies have been performed in following mediums: 1. Ph 1.2 HCl buffer 2. Ph 4.5 Acetate buffer 3. Ph 6.8 Phosphate buffer		
		1 ' 1 1'	
Analytical method validation/verification of product	Method validation studies have submitte linearity, range, accuracy, precision, specif	•	

		T			
Manufacturer of API		M/S Jiangsu Yogan Pharmaceutical Co., Ltd, China			
API Lot No.		DPG-201803001			
Description of Pack (Container closure system)		Alu/alu blister			
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time Period		Real time: 24 months Accelerated: 6 months			
Frequency		Accelerated: 1,2,3,4 & 6 (Months) Real Time: 3, 6, 9, 12,18 & 24 (Months)			
Batch	No.	19SB-204-01	19SB-205-02	19SB-206-03	
Batch	Size	1500 Tablets	1500 Tablets	1500 Tablets	
Manu	facturing Date	01-2019	01-2019	01-2019	
Date of	of Initiation	24-01-2019	24-01-2019	24-01-2019	
No. of Batches			03		
Administrative Portion					
1.	Reference of previous approval of applications with stability study data of the firm (if any)		Not applicable		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Copy of GMP certificate No. JS20160548 issued to M/s Jiangsu Yongan pharmaceuticals Co., Ltd, China, Address: No.18, 237 Provincial highway, Jiangsu HUai an economic Development Zone Issued by China Food and drug administration. Valid up to 03-03-2021.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Commercial Invoice No ZY18031601G/W Dated: 16-03-2018 from Suzhou ZhiYu Biotechnology Co., Ltd is submitted & attested by ADC (Karachi) dated ;09-04-2018.		
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		Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)				

Remarks of Evaluator^{II}:

• The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 296th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 296th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 296th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek
	Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek
	Road Karachi
Brand Name	Fludip 10mg tablet

Batch No. of drug pr	roduct	19SB-	-204-01	19	SB-205-02	19SB-2	206-03		
Case No.		3							
Registration	Board	296 th	meeting	of	Registration	Board	held	on	8-9 th
meeting		Septer	mber, 2020).					

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 296th meeting:
 - ➤ Method used for analysis of API along with COA.
 - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
 - Record of comparative dissolution data against the reference product of Forxiga tablet.
 - ➤ Complete batch manufacturing record of three stability batches.
 - Finished drug product analytical method validation
 - ➤ Reports of stability studies of API from manufacturer.
 - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

- > OOS.
- > Pharmaceutical Equivalence studies.
- > Process validation protocol.
- ➤ Analytical method validation studies for drug 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.

•	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore		
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi		
	Status of the applicant	 ☐ Manufacturer ☐ Importer ☑ Is involved in none of the above (contract giver) 		
	Status of application	☑ New Drug Product (NDP)☐ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	□ Domestic sale□ Export sale☑ Domestic and Export sales		
	Dy. No. and date of submission	Dy.No 1014 dated 11-01-2022		
	Details of fee submitted	Rs.75,000/- dated 25-11-2021		
	The proposed proprietary name / brand name	Dapazin 5mg Tablet		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin5mg		
	Pharmaceutical form of applied drug	Oblong, Dark Red color, Biconvex, film coated tablet, plain from both sides		
	Pharmacotherapeutic Group of (API)	Anti-Diabetic		
	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	Farxiga tablet of USFDA approved
For generic drugs (me-too status)	Dapaglu 5mg tablet of M/s Scotmann
GMP status of the Finished product	New GMP granted on 07/10/2021
manufacturer	Tablet section (General & Psycotropic) approved.
Name and address of API manufacturer.	M/s Jiangsu Yogan Pharmaceutical Co., Ltd, China
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-template. Summarized information related nomenclature, structure, general propert solubilities, physical form, manufacturers, descript of manufacturing process and controls, impurit specifications, analytical procedures and verification, batch analysis and justification specification, reference standard, container closs system and stability studies of drug substance and deproduct is submitted.
Module III (Drug Substance)	The firm as submitted detail of nomenclature, struct general properties, solubilities, physical for manufacturers, description of manufacturing product and controls, tests for impurity & related substant specifications, analytical procedures and its validate batch analysis and justification of specification reference standard, container closure system stability studies of drug substance
Stability studies	The firm has submitted copy of accelerated, 06 Mor $(40^{\circ}\text{C} \pm 2^{\circ}\text{C} \& 75\pm5\%\text{RH})$ & long term, 06 Mor $(30^{\circ}\text{C} \pm 2^{\circ}\text{C} \& 65\pm5\%\text{RH})$ stability study reports of batches.
Module-III (Drug Product):	The firm has submitted detail of manufacture description of manufacturing process and contribution impurities, specifications, analytical process (including dissolution testing at acidic and but medium) and its validation studies, batch analysis justification of specification, reference stands container closure system and stability studies of diproduct.
Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Comparative dissolution study their product (Flucid Tablets) with Innovator's Brat "Forxiga Tablets" The details are as follows: Feature Reference. Product Genix
	Feature Reference. Product
	Brand Name Forxiga 5mg Flucid 5mg
	Tablet
	Batch No. NJ535 19SB-201-01
	Mfg. Date 03/2017 01-2019
	Exp. Date 02/2020 01-2021
	Comparative dissolution studies have been perform in following mediums: pH 1.2 HCl buffer pH 4.5 Acetate buffer

				pH 6.8 Phosphate buffer		
				Method validation studies have submitted including		
	· ·		linearity, range, accuracy, precision, specificity.			
		STABILITY	S	ΓUDY DATA		
Manu	facturer of API	M/S Jiangsu Yogan Pha	arr	maceutical Co., Ltd, China		
API L	Lot No.	DPG-201803001				
	ription of Pack ainer closure system)	Alu/alu blister				
Stabil	ity Storage Condition	Real time: 30°C ± 2°C / Accelerated: 40°C ± 2°C				
Time	Period	Real time: 24 months Accelerated: 6 months	Real time: 24 months			
Frequ	ency	Accelerated: 1,2,3,4 & 6 (Months) Real Time: 3, 6, 9, 12,18 & 24 (Months)				
Batch	No.	19SB-201-01		19SB-202-02	19SB-203-03	
Batch	Size	1500 Tablets		1500 Tablets	1500 Tablets	
Manu	facturing Date	01-2019		01-2019	01-2019	
Date of	of Initiation	21-01-2019		21-01-2019	21-01-2019	
No. of	f Batches			03		
		Administr	ati	ive Portion		
1.	Reference of previous with stability study data	approval of application of the firm (if any)	ns	Not appl	icable	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			Copy of GMP certificate No. Jiangsu Yongan pharmace Address: No.18, 237 Provinc an economic Development Z and drug administration. Val	uticals Co., Ltd, China, ial highway, Jiangsu HUai one Issued by China Food	
3. Documents for the procurement of API with approval from DRAP (in case of import).		th	Commercial Invoice No ZY1 03-2018 from Suzhou ZhiYu submitted & attested by AD 2018.	Biotechnology Co., Ltd is		
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		&	Submitted		
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Submi	tted			

• The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 296th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 296th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 296th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek				
	Road Karachi				
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek				
	Road Karachi				
Brand Name	Fludip 5mg tablet				
Batch No. of drug product	19SB-201-01 19SB-202-02 19SB-203-03				
Case No.	2				
Registration Board	296 th meeting of Registration Board held on 8-9 th				
meeting	September, 2020.				

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 296th meeting:
 - ➤ Method used for analysis of API along with COA.
 - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
 - > Record of comparative dissolution data against the reference product of Forxiga tablet.
 - > Complete batch manufacturing record of three stability batches.
 - Finished drug product analytical method validation
 - > Reports of stability studies of API from manufacturer.
 - ➤ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

- > QOS.
- Pharmaceutical Equivalence studies.
- Process validation protocol.
- Analytical method validation studies for drug 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.

14.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore	
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi	
	Status of the applicant	 ☐ Manufacturer ☐ Importer ☑ Is involved in none of the above (contract giver) 	
	Status of application	☑ New Drug Product (NDP)☐ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	 □ Domestic sale □ Export sale ☑ Domestic and Export sales 	
	Dy. No. and date of submission	Dy.No 30263 dated 05-11-2021	
	Details of fee submitted	PKR 75,000/-: dated 12/10/2021	
	The proposed proprietary name / brand name	Erglif-M Tablets 2.5mg/1000mg	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ertugliflozin L-Pyroglutamic acid eq. to Ertugliflozin	

Pharmaceutical form of applied drug	Oblong, Dark Red color, Biconvex, film coated table plain from both sides
Pharmacotherapeutic Group of (API)	Anti-Diabetic
Reference to Finished product specifications	Innovator Specification
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	SEGLUROMET tablet 2.5mg/1000mg by Merck & Co Inc, USA (USFDA Approved)
For generic drugs (me-too status)	LOZGIL -M Tablets 2.5mg/1000mg by Genix Pharm Private Limited.
GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Tablet section (General & Psycotropic) approved.
Name and address of API manufacturer.	Ertugliflozin: Shanghai Pharma Group Changzho Kony Pharmaceutical Co., Ltd Address: Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China Metformin HCL: Abhilash Chemicals and Pharmaceuticals Private Limited, Address: 34/6A, Nayakkanpatti Village, Madur North Taluk, Madurai. Pin Code — 625301. Tam Nadu, INDIA.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-P template. Summarized information related nomenclature, structure, general propertie solubilities, physical form, manufacturers, description of manufacturing process and controls, impuritie specifications, analytical procedures and inverification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drup product is submitted.
Module III (Drug Substance)	Drug substances is tested at Ertugliflozin on in-house specifications & Metformin HCL on US Specifications. The firm as submitted detail of nomenclature, structure, general properties solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specification analytical procedures and its validation, batch analyst and justification of specification, reference standard container closure system and stability studies of drug substance
Stability studies	Stability study conditions: Ertugliflozin: Real time: 30° C \pm 2° C $/$ 65% \pm 5% RH for 24 months Accelerated: 40° C \pm 2° C $/$ 75% \pm 5% RH for 6 month Batches: (ETG20161201, ETG20161202 ETG20170101) Metformin HCL: Real time: 30° C \pm 2° C $/$ 65% \pm 5% RH for 60 months Accelerated: 40° C \pm 2° C $/$ 75% \pm 5% RH for 6 month Batches: (MET/06/00546, MET/06/00547

			MET/06/00548)		
	Module-III (Drug Produ	ict):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.		
Pharmaceutical equivalence and comparative dissolution profile			Pharmaceutical Equivalence have been established against the brand leader that is SEGLUROMET tablet 2.5mg/1000mg (Batch no: S037765) by Merck & Co. Inc by performing quality tests (Identification, Assay, Disintegration, Dissolution) CDP has been performed against the same brand that is SEGLUROMET tablet 2.5mg/1000mg Merck & Co. Inc in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 value was in acceptable range.		
	Analytical method v product	alidation/verification of	Method validation studies h linearity, range, accuracy, pre	e e e e e e e e e e e e e e e e e e e	
	-	STABILITY S	TUDY DATA		
Manu	facturer of API	Ltd China Daixi street, Lu Metformin hydrochlori	Pharma Group Changzhou ko Loyang town, Wujin District, C de: Abhilash Chemicals and lage, Madurai North Taluk Mad	Changzhou, Jiangsu, China Pharmaceuticals Pvt. Ltd.	
API L	ot No.	Ertugliflozin: ETG20180	0901, Metformin HCL : MET	/B/01/19030070	
	iption of Pack niner closure system)	Alu/alu blister			
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: 24 months Accelerated: 6 months			
Frequ	ency	Accelerated: 1,2,3,4 & 6 Real Time: 3, 6, 9,12,18			
Batch	No.	20SB-014-01	20SB-015-02	20SB-016-03	
Batch	Size	1500 Tablets	1500 Tablets	1500 Tablets	
Manu	facturing Date	01-2020	01-2020	01-2020	
Date of	of Initiation	10-03-2020	10-03-2020	10-03-2020	
No. of	Batches		03		
Administrative Portion					
1.	1. Reference of previous approval of applications with stability study data of the firm (if any)		Not applicable		
Approval of API/ DML/GMP certificate of API 2. manufacturer issued by concerned regulatory authority of country of origin.		Ertugliflozin: Firm has sucertificate (No. JS20170734). The certificate is valid till 25-Metformin: Firm has sucertificate (No. 14957/D. Department of Food and Drug Government of Tamilnadu certificate was valid till 31-12	bissued by CFDA China. -12-2022. bmitted copy of GMP 01/4/2021) issued by gs Control Administration dated 10-01-2022. The		

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Ertugliflozin: Firm has submitted copy of commercial invoice cleared dated 12-10-2018 specifying import of 500g Ertugliflozin. The invoice is signed by AD (I&E) DRAP Karachi office dated 12-10-2018. Metformin: Firm has submitted copy of commercial invoice cleared dated 22-03-2019 specifying import of 3500kg metformin HCl. The invoice is signed 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.	
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)	

• The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 316th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 316th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 316th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek			
	Road Karachi			
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek			
	Road Karachi			
Brand Name	ERTOZIN-M TABLET 2.5MG/1000mg			
Batch No. of drug product	20SB-014-01 20SB-015-02 20SB-016-03			
Case No.	727			
Registration Board	316 th meeting of Registration Board held on 15 th , 16 th & 17 th			
meeting	March, 2022			

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
 - Method used for analysis of API along with COA.
 - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
 - > Record of comparative dissolution data against the reference product of Segluromet tablet.
 - > Complete batch manufacturing record of three stability batches.
 - Finished drug product analytical method validation
 - Reports of stability studies of API from manufacturer.
 - ➤ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- > OOS.
- > Pharmaceutical Equivalence studies.
- > Process validation protocol.
- ➤ Analytical method validation studies for drug product.

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 validate submitted in the registration application.	ion of first three batches as per the commitment	
15.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore	
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi	
	Status of the applicant	 ☐ Manufacturer ☐ Importer ☑ Is involved in none of the above (contract giver) 	
	Status of application	☑ New Drug Product (NDP)☐ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	 □ Domestic sale □ Export sale ☑ Domestic and Export sales 	
	Dy. No. and date of submission	Dy.No 29158 dated 26-10-2021	
	Details of fee submitted	Rs.75,000/- dated 12-10-2021	
	The proposed proprietary name / brand name	Erglif-M Tablets 7.5mg/1000mg	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ertugliflozin L-Pyroglutamic acid eq. to Ertugliflozin	
	Pharmaceutical form of applied drug	Oblong, Dark Red color, Biconvex, film coated tablet, plain from both sides	
	Pharmacotherapeutic Group of (API)	Anti-Diabetic	
	Reference to Finished product specifications	Innovator Specification	
	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	SEGLUROMET tablet 2.5mg/1000mg by Merck & Co. Inc, USA (USFDA Approved)	
	For generic drugs (me-too status)	LOZGIL -M Tablets 2.5mg/1000mg by Genix Pharma Private Limited.	
	GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Tablet section (General & Psycotropic) approved.	
	Name and address of API manufacturer.	Ertugliflozin: Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd Address: Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China Metformin HCL: Abhilash Chemicals and Pharmaceuticals Private Limited, Address: 34/6A, Nayakkanpatti Village, Madurai	
		North Taluk, Madurai. Pin Code – 625301. Tamil Nadu, 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 Substa	ance)	Drug substances is tested at Ertugliflozin on in-house specifications & Metformin HCL on USP Specifications. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance	
Stability studies		Stability study conditions: Ertugliflozin: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 24 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months Batches: (ETG20161201, ETG20161202 & ETG20170101) Metformin HCL: 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: (MET/06/00546, MET/06/00547 & MET/06/00548)	
Module-III (Drug Produ	act):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.	
Pharmaceutical equiva dissolution profile	llence and comparative	Pharmaceutical Equivalence have been established against the brand leader that is SEGLUROMET tablet 7.5mg/1000mg (Batch no: S037722) by Merck & Co. Inc by performing quality tests (Identification, Assay, Disintegration, Dissolution) CDP has been performed against the same brand that is SEGLUROMET tablet 7.5mg/1000mg (Batch no: S037722) Merck & Co. Inc in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 value was in acceptable range.	
Analytical method validation/verification of product		Method validation studies have submitted including linearity, range, accuracy, precision, specificity.	
	STABILITY S	TUDY DATA	
Manufacturer of API	Ltd China Daixi street, Lu Metformin hydrochlori	Pharma Group Changzhou kony Pharmaceuticals Co., aoyang town, Wujin District, Changzhou, Jiangsu, China de: Abhilash Chemicals and Pharmaceuticals Pvt. Ltd. age, Madurai North Taluk Madurai Tamilnadu India.	
API Lot No.	Ertugliflozin: ETG20180	0901, Metformin HCL : MET/B/01/19030070	
Description of Pack	Alu/alu blister		

(Cont	tainer closure 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: 24 months Accelerated: 6 months		
Frequ	iency	Accelerated: 1,2,3,4 & 6 Real Time: 3, 6, 9, 12,18		
Batch	ı No.	20SB-026-01	20SB-027-02	20SB-028-03
Batch	n Size	1500 Tablets	1500 Tablets	1500 Tablets
Manu	ıfacturing Date	02-2020	02-2020	02-2020
Date	of Initiation	25-03-2020	25-03-2020	25-03-2020
No. o	f Batches		03	
		Administrat	ive Portion	
1.	Reference of previous with stability study data	approval of applications a of the firm (if any)	Not appl	icable
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).		Ertugliflozin: Firm has submitted copy of commercial invoice cleared dated 12-10-2018 specifying import of 500g Ertugliflozin. The invoice is signed by AD (I&E) DRAP Karachi office dated 12-10-2018. Metformin: Firm has submitted copy of commercial invoice cleared dated 22-03-2019 specifying import of 3500kg metformin HCl. The invoice is signed by AD (I&E) DRAP Karachi.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Submitted	
5.	Compliance Pocard of UDI C coftware 21CEP &		Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			

• The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 316th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 316th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 316th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek	
	Road Karachi	

Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek		
	Road Karachi		
Brand Name	ERTOZIN-M TABLET 7.5MG/1000mg		
Batch No. of drug product	20SB-026-01 20SB-027-02 20SB-028-03		
Case No.	722		
Registration Board	316 th meeting of Registration Board held on 15 th , 16 th & 17 th		
meeting	March, 2022		

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
 - ➤ Method used for analysis of API along with COA.
 - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
 - Record of comparative dissolution data against the reference product of Segluromet tablet.
 - > Complete batch manufacturing record of three stability batches.
 - Finished drug product analytical method validation
 - > Reports of stability studies of API from manufacturer.
 - ➤ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

- > OOS.
- > Pharmaceutical Equivalence studies.
- Process validation protocol.
- ➤ Analytical method validation studies for drug 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.

16.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore	
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi	
	Status of the applicant	 ☐ Manufacturer ☐ Importer ☑ Is involved in none of the above (contract giver) 	
	Status of application	☑ New Drug Product (NDP)☐ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	 □ Domestic sale □ Export sale ☑ Domestic and Export sales 	
	Dy. No. and date of submission	Dy.No 29990 dated 03-11-2021	
	Details of fee submitted	Rs.75,000/- dated 22-10-2021	
	The proposed proprietary name / brand name	Erglif-M 2.5mg/500mg Tablet	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ertugliflozin L-Pyroglutamic acid eq. to Ertugliflozin	
	Pharmaceutical form of applied drug	Oblong, Dark Red color, Biconvex, film coated tablet, plain from both sides	

Pharmacotherapeutic Group of (API)	Anti-Diabetic
Reference to Finished product specifications	Innovator Specification
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	SEGLUROMET tablet 2.5mg/500mg by Merck & Co Inc, USA (USFDA Approved)
For generic drugs (me-too status)	ERTUVIA-M Tablets 2.5mg/500mg by Ferozsons Laboratories Private limited.
GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Tablet section (General & Psycotropic) approved.
Name and address of API manufacturer.	Ertugliflozin: Shanghai Pharma Group Changzho Kony Pharmaceutical Co., Ltd Address: Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China Metformin HCL: Abhilash Chemicals and Pharmaceuticals Private Limited, Address: 34/6A, Nayakkanpatti Village, Madura North Taluk, Madurai. Pin Code — 625301. Tam Nadu, INDIA.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-P template. Summarized information related nomenclature, structure, general propertie solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities specifications, analytical procedures and inverification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drup product is submitted.
Module III (Drug Substance)	Drug substances is tested at Ertugliflozin on in-hou specifications & Metformin HCL on US Specifications. The firm as submitted detail nomenclature, structure, general properties solubilities, physical form, manufacturers, description of manufacturing process and controls, tests frimpurity & related substances, specification analytical procedures and its validation, batch analyst and justification of specification, reference standar container closure system and stability studies of drugsubstance
Stability studies	Stability study conditions: Ertugliflozin: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 24 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 month Batches: (ETG20161201, ETG20161202 ETG20170101) Metformin HCL: 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 month Batches: (MET/06/00546, MET/06/00547

	Pharmaceutical equivalence and comparative dissolution profile		description of manufacturing impurities, specifications, (including dissolution testin medium) and its validation stripustification of specification container closure system and product. Pharmaceutical Equivalence against the brand leader that is 2.5mg/500mg (Batch no: S03' by performing quality tests Disintegration, Dissolution) CDP has been performed agai SEGLUROMET tablet 2.5m Inc in Acid media (0.1N HCI' & Phosphate Buffer (pH 6.8 acceptable range.	analytical procedure g at acidic and buffer udies, batch analysis and on, reference standard, stability studies of drug have been established SEGLUROMET tablet 7765) by Merck & Co. Inc. (Identification, Assay, nst the same brand that is mg/500mg Merck & Co.), acetate buffer (pH 4.5)
	Analytical method v	validation/verification of	Method validation studies had linearity, range, accuracy, pre	e
	product	STABILITY S		cision, specificity.
Manut	Manufacturer of API Ertugliflozin: Shanghai Ltd China Daixi street, Lu Metformin hydrochlori		Pharma Group Changzhou ko loyang town, Wujin District, Cl de: Abhilash Chemicals and Page, Madurai North Taluk Mad	hangzhou, Jiangsu, China Pharmaceuticals Pvt. Ltd.
API L	ot No.	Ertugliflozin: ETG20180	0901, Metformin HCL: MET/	B/01/19030070
	iption of Pack ainer 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: 24 months Accelerated: 6 months				
		Accelerated: 1,2,3,4 & 6 Real Time: 3, 6, 9, 12,18		
Batch	No.	20SB-008-01	20SB-009-02	20SB-010-03
Batch	Size	1500 Tablets	1500 Tablets	1500 Tablets
Manut	facturing Date	01-2020	01-2020	01-2020
Date of	of Initiation	03-03-2020	03-03-2020	03-03-2020
No. of	Batches		03	
	I	Administrat	I	
1.	Reference of previous approval of applications with stability study data of the firm (if any)		Not applicable	
Approval of API/ DML/GMP certificate of API 2. manufacturer issued by concerned regulatory authority of country of origin.		INIATIATION HITM HAS SHAMHED CONV OF LAMP		
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Ertugliflozin: Firm has submitted copy of commercial invoice cleared dated 12-10-2018 specifying import of	

		500g Ertugliflozin. The invoice is signed by AD (I&E) DRAP Karachi office dated 12-10-2018. Metformin: Firm has submitted copy of commercial invoice cleared dated 22-03-2019 specifying import of 3500kg metformin HCl. The invoice is signed 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.	
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)	

• The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 322nd meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 322nd meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 322nd meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek		
	Road Karachi		
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek		
	Road Karachi		
Brand Name	ERTOZIN-M TABLET 2.5mg/500mg		
Batch No. of drug product	20SB-008-01 20SB-009-02 20SB-010-03		
Case No.	19		
Registration Board	322 nd meeting of Registration Board held on 8 th & 10 th		
meeting	November, 2022		

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
 - Method used for analysis of API along with COA.
 - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
 - > Record of comparative dissolution data against the reference product of Segluromet tablet.
 - ➤ Complete batch manufacturing record of three stability batches.
 - Finished drug product analytical method validation
 - ➤ Reports of stability studies of API from manufacturer.
 - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- > QOS.
- Pharmaceutical Equivalence studies.
- > Process validation protocol.
- Analytical method validation studies for drug 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.

7.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore	
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi	
	Status of the applicant	 ☐ Manufacturer ☐ Importer ☑ Is involved in none of the above (contract giver) 	
	Status of application	New Drug Product (NDP)□ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	 □ Domestic sale □ Export sale ☑ Domestic and Export sales 	
	Dy. No. and date of submission	Dy. No 29159 dated 26-10-2021	
	Details of fee submitted	Rs.75,000/- dated 12-10-2021	
	The proposed proprietary name / brand name	Erglif-M 7.5mg/500mg Tablet	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ertugliflozin L-Pyroglutamic acid eq. to Ertugliflozin	
	Pharmaceutical form of applied drug	Oblong, Dark Red color, Biconvex, film coated tablet, plain from both sides	
	Pharmacotherapeutic Group of (API)	Anti-Diabetic Anti-Diabetic	
	Reference to Finished product specifications	Innovator Specification	
	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	SEGLUROMET tablet 7.5mg/500mg by Merck & Co. Inc, USA (USFDA Approved)	
	For generic drugs (me-too status)	ERTUVIA-M Tablets 7.5mg/500mg by Ferozsons Laboratories Private limited.	
	GMP status of the Finished product	New GMP granted on 07/10/2021	
	manufacturer	Tablet section (General & Psycotropic) approved.	
	Name and address of API manufacturer.	Ertugliflozin: Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd Address: Daixi Street, Luoyang Town, Wujin District, Changzhou, Jiangsu, 213105, China Metformin HCL: Abhilash Chemicals and	
		Pharmaceuticals Private Limited, Address: 34/6A, Nayakkanpatti Village, Madurai North Taluk, Madurai. Pin Code – 625301. Tamil Nadu, 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 Substa	ance)	Drug substances is tested at Ertugliflozin on in-house specifications & Metformin HCL on USP Specifications. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies		Stability study conditions: Ertugliflozin: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 24 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months Batches: (ETG20161201, ETG20161202 & ETG20170101) Metformin HCL: 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: (MET/06/00546, MET/06/00547 & MET/06/00548)
Module-III (Drug Produ	ict):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile		Pharmaceutical Equivalence have been established against the brand leader that is SEGLUROMET tablet 7.5mg/500mg (Batch no: S037765) by Merck & Co. Inc by performing quality tests (Identification, Assay, Disintegration, Dissolution) CDP has been performed against the same brand that is SEGLUROMET tablet 7.5mg/500mg Merck & Co. Inc in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 value was in acceptable range.
Analytical method v product	alidation/verification of	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
	STABILITY S	TUDY DATA
Manufacturer of API Ltd China Daixi street, Ltd Metformin hydrochloric		Pharma Group Changzhou kony Pharmaceuticals Co., aoyang town, Wujin District, Changzhou, Jiangsu, China de: Abhilash Chemicals and Pharmaceuticals Pvt. Ltd. age, Madurai North Taluk Madurai Tamilnadu India.
API Lot No.	Ertugliflozin: ETG20180	0901, Metformin HCL : MET/B/01/19030070
Description of Pack (Container closure system) Alu/alu blister		
Stability 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		
Frequ	iency	Accelerated: 1,2,3,4 & 6 Real Time: 3, 6, 9, 12,18		
Batch	ı No.	20SB-020-01	20SB-021-03	20SB-022-03
Batch	n Size	1500 Tablets	1500 Tablets	1500 Tablets
Manu	ıfacturing Date	02-2020	02-2020	02-2020
Date	of Initiation	16-03-2020	16-03-2020	16-03-2020
No. c	of Batches		03	
	_	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.		Ertugliflozin: Firm has submitted copy of GMP certificate (No. JS20170734) issued by CFDA China. The certificate is valid till 25-12-2022. Metformin: Firm has submitted copy of GMP certificate (No. 14957/D1/4/2021) issued by Department of Food and Drugs Control Administration Government of Tamilnadu dated 10-01-2022. The certificate was valid till 31-12-2024.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Ertugliflozin: Firm has submitted copy of commercial invoice cleared dated 12-10-2018 specifying import of 500g Ertugliflozin. The invoice is signed by AD (I&E) DRAP Karachi office dated 12-10-2018. Metformin: Firm has submitted copy of commercial invoice cleared dated 22-03-2019 specifying import of 3500kg metformin HCl. The invoice is signed 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.		e Submitted	
5.	Compliance Record of HPI C software 21CFR &		Submitted	
6.	Record of Digital data logger for temperature and			

• The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 322nd meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 322nd meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 322nd meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek	
	Road Karachi	
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek	
	Road Karachi	
Brand Name	ERTOZIN-M TABLET 7.5mg/500mg	

Batch No. of drug	product	20SB-020	0-01	20SB-021-03	20SB-02	22-03	
Case No.		18					
Registration	Board	322 nd me	eting of	Registration	Board held	on 8th &	10 th
meeting		Novembe	er, 2022				

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
 - ➤ Method used for analysis of API along with COA.
 - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
 - Record of comparative dissolution data against the reference product of Segluromet tablet.
 - ➤ Complete batch manufacturing record of three stability batches.
 - Finished drug product analytical method validation
 - > Reports of stability studies of API from manufacturer.
 - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

- > OOS.
- > Pharmaceutical Equivalence studies.
- > Process validation protocol.
- Analytical method validation studies for drug 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.	
Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore
Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Status of the applicant	 ☐ Manufacturer ☐ Importer ☑ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)
Intended use of pharmaceutical product	□ Domestic sale□ Export sale☑ Domestic and Export sales
Dy. No. and date of submission	Dy.No 32072 dated 23-11-2021
Details of fee submitted	Rs.75,000/- dated 16-11-2021
The proposed proprietary name / brand name	Dactril Capsule 100mg
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Racecadotril 100mg
Pharmaceutical form of applied drug	White color powder filled in Maroon color body & cap of Hard Gelatin Capsule Size "2"
Pharmacotherapeutic Group of (API)	Anti-diarrheal
Reference to Finished product specifications	As per innovator's specifications
Proposed Pack size	10's
Proposed unit price	As per PRC

The status in reference regulatory authorities	Hidrasec Capsules by M/s Abbott Laboratories. Approved.
For generic drugs (me-too status)	Hidrasec Capsules by M/s Abbott Laboratories. Approved.Reg no: 087518
GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Sachet section approved.
Name and address of API manufacturer.	M/s Symed labs limited. Unit-II, Plot No. 25/B, Phas III, I.D.A, Jeedimetla (Village), Quthbullap (Mandal), Medchal-Malkajgiri (Dist) – 500 05 Telangana, INDIA
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-I template. Summarized information related nomenclature, structure, general propertic solubilities, physical form, manufacturers, description of manufacturing process and controls, impuritive specifications, analytical procedures and verification, batch analysis and justification specification, reference standard, container closus system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)	Racecadotril is non-pharmacopeial. The firm has submitted detail of nomenclature, structure, gene properties, solubilities, physical form, manufacture description of manufacturing process and controls, te for impurity & related substances, specification analytical procedures and its verification, bat analysis and justification of specification, referent standard, container closure system and stability studiof drug substance.
Stability studies	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 60 month Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 month Batches: (RAC L009, RAC L010 & RAC L011)
Module-III (Drug Product):	The firm has submitted detail of manufacture description of manufacturing process and contro impurities, specifications, analytical procedure, validation studies, batch analysis and justification specification, reference standard, container closusystem and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been establish against the brand leader that is Hidrasec (B#SX554) ABBOTT by performing quality tests (Identification Assay, Disintegration Dissolution) CDP has been performed against the same brand that Hidrasec (B#SX554) by ABBOTT, in Acid med (0.1N HCl), acetate buffer 4.5 & Phosphate Buffer p. (6.8). The f2 value was in acceptable range.
Analytical method validation/verification of product	Method validation studies have been submittincluding linearity, range, accuracy, precision specificity, robustness and justification of systems.
	suitability

Manufacturer of API		Symed Labs Limited			
API I	Lot No.	2KA0261119			
	ription of Pack tainer closure system)	Alu/Alu			
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: 1,2,3,4 & 6 (Months) Real Time: 3, 6, 9, 12,18 & 24 (Months)			
Batch	n No.	20SB(A)-133-01	20SB(A)-134-02	20SB(A)-135-03	
Batch	n Size	1500 Capsules	1500 Capsules	1500 Capsules	
Manu	facturing Date	08-2020	08-2020	08-2020	
Date of Initiation		20-08-2020	20-08-2020	20-08-2020	
No. of Batches		03			
Administrat			ive Portion		
1.	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.		Copy of GMP certificate vali	d till 17/12/2021	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Copy of Purchase invoice No 19/02/2020 is		
4.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Submitted		
5.	5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Submi	tted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Submi	tted	

Remarks of Evaluator:

• The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 324th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 324th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 324th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek		
	Road Karachi		
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek		
	Road Karachi		
Brand Name	Racetril capsule 100mg		
Batch No. of drug product	20SB-133-01 20SB-134-02 20SB-135-03		
Case No.	1318		
Registration Board	324 th meeting of Registration Board held on 24 th to 26 th		
meeting	January, 2024		

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
 - Method used for analysis of API along with COA.
 - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
 - > Record of comparative dissolution data against the reference product of Hidrasec capsule.
 - > Complete batch manufacturing record of three stability batches.
 - Finished drug product analytical method validation.
 - Reports of stability studies of API from manufacturer.
 - ➤ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- > Pharmaceutical equivalence studies
- > QOS.
- > Process validation protocol.
- ➤ Analytical method validation studies for drug product.

Sr.#	Section#	Observation	Response
1.	1.6.5	Valid GMP certificate of drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate in the name of M/s Symed Labs Limited., Plot No. 25/B, Phase-III, IDA, Jeedimetla Village, Quthbullapur Mandal, Medchal - Malkajgiri District, Pincode 500005, Telangana State, India., issued by Deputy Director and Certifying Authority Drugs Control Administration Telangana State India valid upto 24-04-2023.
2.	3.2.8.5	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer shall be submitted. Analytical Method Verification studies including specificity, accuracy and repeatability	Submitted.

		(method precision) performed by the Drug Product manufacturer shall be submitted.	
3.	3.2.P.5	Justification shall be submitted for not including dissolution test in the drug product specifications	Firm has referred to the submitted batch analysis certificates and stability studies wherein dissolution test has been performed.
4.	3.2.P.8	Documents confirming import of API shall be submitted, attested from DRAP I&E office.	Firm has submitted readable copy of invoice No. EXP/1334 dated 19-02-2020 for import of 0.85kg of Racecadotril (Batch#2KA0261119) in name of M/s Genix Pharma (Pvt.) Ltd attested by AD (I&E) DRAP Karachi dated 17-03-2020.

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.

9.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	 ☐ Manufacturer ☐ Importer ☑ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	 □ Domestic sale □ Export sale ☑ Domestic and Export sales
	Evidence of required manufacturing facility	Sachet general section approval confirmed form the copy of renewal of DML letter submitted dated 20-09-2021.
	Dy. No. and date of submission	Dy.No 30932 dated 11-11-2021
	Details of fee submitted	Rs.75,000/- dated 25-10-2021
	The proposed proprietary name / brand name	Dactril sachet 30mg

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Racecadotril30mg
Pharmaceutical form of applied drug	Free flowing white granules
Pharmacotherapeutic Group of (API)	Anti-diarrheal
Reference to Finished product specifications	As per innovator's specifications
Proposed Pack size	16's
Proposed unit price	As per PRC
The status in reference regulatory authorities	Hidrasec by M/s Abbott laboratories approved MHRA of UK
For generic drugs (me-too status)	Hidrasec by M/s Abbott laboratories. Approved.Reg no: 087082
GMP status of the Finished product manufacturer	New GMP granted on 07/10/2021 Sachet sec approved.
Name and address of API manufacturer.	M/s Symed labs limited. Unit-II, Plot No. 25/B, Phase-III, I.D.A, Jeedimetla (Village), Quthbulla (Mandal), Medchal-Malkajgiri (Dist) – 500 (Telangana, INDIA
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS template. Summarized information related nomenclature, structure, general proper solubilities, physical form, manufacturers, descrip of manufacturing process and controls, impuris specifications, analytical procedures and verification, batch analysis and justification specification, reference standard, container clossystem and stability studies of drug substance and oproduct is submitted.
Module III (Drug Substance)	Racecadotril is non-pharmacopeial. The firm submitted detail of nomenclature, structure, gen properties, solubilities, physical form, manufactur description of manufacturing process and controls, t for impurity & related substances, specificationallytical procedures and its verification, be analysis and justification of specification, refere standard, container closure system and stability studof drug substance.
Stability studies	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 60 mont Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 mon Batches: (RAC L009, RAC L010 & RAC L011)
Module-III (Drug Product):	The firm has submitted detail of manufacture description of manufacturing process and contributions, specifications, analytical procedure, validation studies, batch analysis and justification specification, reference standard, container clossystem and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been establish against the brand leader that is Hidrasec (B#SXE22) by ABBOTT by performing quality (Identification, Assay, Disintegration Dissolution) CDP is not applicable.

	Analytical method v product	validation/verification of	Method validation studies including linearity, range specificity, robustness and suitability	e, accuracy, precision,	
		STABILITY S'	TUDY DATA		
Manu	facturer of API	1	. Unit-II, Plot No. 25/B, Pha (Mandal), Medchal-Malkaj		
API L	Lot No.	2KA0261119			
	ription of Pack rainer closure system)	Sachet foil			
Stabil	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	Period	Real time: 6 months Accelerated: 6 months			
Frequ	ency	Accelerated: 3 & 6 (Mon Real Time: 3, 6, 9, 12, 18	*		
Batch	No.	20SB(A)-028-01	20SB(A)-029-02	20SB(A)-030-03	
Batch	Size	1500 Sachets	1500 Sachets	1500 Sachets	
Manu	facturing Date	12-2020	12-2020	12-2020	
Date	of Initiation	04-01-2021	04-01-2021	04-01-2021	
No. of Batches			03		
		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.			d till 17/12/2021	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Copy of Purchase invo dated 19/02/2020		
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 HPI C coffware 21CFR &		Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			tted	
D	wkg of Evolution II.				

• The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 324th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 324th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 324th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek
	Road Karachi

Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek	
	Road Karachi	
Brand Name	Racetril sachet 30mg	
	-	
Batch No. of drug product	20SB(A)-028-01 20SB(A)-029-02 20SB(A)-030-03	
Case No.	1317	
Registration Board	324 th meeting of Registration Board held on 24 th to 26 th	
meeting	January, 2024	

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
 - Method used for analysis of API along with COA.
 - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
 - Record of Pharmaceutical equivalence data against the reference product of Hidrasec sachet.
 - > Complete batch manufacturing record of three stability batches.
 - Finished drug product analytical method validation
 - Reports of stability studies of API from manufacturer.
 - ➤ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

- > QOS.
- Process validation protocol.

Analytical method validation studie	es for drug product.
Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore
Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Status of the applicant	 ☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
Intended use of pharmaceutical product	□ Domestic sale□ Export sale☑ Domestic and Export sales
Evidence of required manufacturing facility	Sachet general section approval confirmed form the copy of renewal of DML letter submitted dated 20-09-2021.
Dy. No. and date of submission	Dy.No 30773 dated 10-11-2021
Details of fee submitted	Rs.75,000/- dated 25-10-2021
The proposed proprietary name / brand name	Dactril sachet 10mg
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Racecadotril10mg
Pharmaceutical form of applied drug	Free flowing white granules
Pharmacotherapeutic Group of (API)	Anti-diarrheal
Reference to Finished product specifications	As per innovator's specifications
Proposed Pack size	16's
Proposed unit price	As per PRC

The status in reference r	regulatory authorities	Hidrasec by M/s Abbott laboratories approved by MHRA of UK
For generic drugs (me-to	oo status)	Hidrasec by M/s Abbott laboratories. Approved.Reg no: 087082
GMP status of the Finishmanufacturer	hed product	New GMP granted on 07/10/2021 Sachet section approved.
Name and address of Al	PI manufacturer.	M/s Symed labs limited. Unit-II, Plot No. 25/B, Phase-III, I.D.A, Jeedimetla (Village), Quthbullapur (Mandal), Medchal-Malkajgiri (Dist) – 500 055, Telangana, INDIA
Module-II (Quality Ove	rall 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 Substa	ance)	Racecadotril is non-pharmacopeial. The firm has submitted detail of nomenclature, structure, general properties, solubilities, 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		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: (RAC L009, RAC L010 & RAC L011)
Module-III (Drug Produ	uct):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equiva dissolution profile	lence and comparative	Pharmaceutical Equivalence have been established against the brand leader that is Hidrasec (B#SXN635) by ABBOTT by performing quality tests (Identification, Assay, Disintegration Dissolution) CDP is not applicable.
Analytical method validation/verification of product		Method validation studies have been submitted including linearity, range, accuracy, precision, specificity, robustness and justification of system suitability
	STABILITY S	TUDY DATA
anufacturer of API		. Unit-II, Plot No. 25/B, Phase-III, I.D.A, Jeedimetla (Mandal), Medchal-Malkajgiri (Dist) – 500 055,
PI Lot No. 2KA0261119		

	iption of Pack ainer closure system)	Sachet foil			
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: 3 & 6 (Mon Real Time: 3, 6, 9, 12,18	*		
Batch	No.	20SB(A)-025-01	20SB(A)-026-02	20SB(A)-027-03	
Batch	Size	1500 Sachets	1500 Sachets	1500 Sachets	
Manu	facturing Date	12-2020	12-2020	12-2020	
Date of	of Initiation	04-01-2021	04-01-2021	04-01-2021	
No. of	f Batches		03		
Administrative Portion					
1.	Reference of previous approval of applications with stability study data of the firm (if any)		Not applicable		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Copy of GMP certificate vali	d till 17/12/2021	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Copy of Purchase invo dated 19/02/2020		
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		Submi	tted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Submi	tted	

Remarks of Evaluator:

• The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 324th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 324th meeting on Form 5D, based on the stability data submission as per checklist approved by Registration Board in its 293rd meeting. The details of the already considered product in 324th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	Racetril sachet 10mg
Batch No. of drug product	20SB(A)-025-01 20SB(A)-026-02 20SB(A)-027-03
Case No.	1316
Registration Board meeting	324 th meeting of Registration Board held on 24 th to 26 th January, 2024

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 316th meeting:
 - ➤ Method used for analysis of API along with COA.
 - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
 - > Record of Pharmaceutical equivalence data against the reference product of Hidrasec sachet.
 - ➤ Complete batch manufacturing record of three stability batches.
 - Finished drug product analytical method validation
 - ➤ Reports of stability studies of API from manufacturer.
 - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In addition to above referred data, which has also been evaluated in application of M/s Genix pharma, the firm has submitted following data also in compliance to the requirements of Form 5F:

- > OOS
- Process validation protocol.
- Analytical method validation studies for drug product.

Sr.#	Section#	Observation	Response
5.	1.6.5	Valid GMP certificate of drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate in the name of M/s Symed Labs Limited., Plot No. 25/B, Phase-III, IDA, Jeedimetla Village, Quthbullapur Mandal, Medchal - Malkajgiri District, Pincode 500005, Telangana State, India., issued by Deputy Director and Certifying Authority Drugs Control Administration Telangana State India valid upto 24-04-2023.
6.	3.2.S.5	 Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer shall be submitted. Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product 	Submitted.

		manufacturer shall be submitted.	
7.	3.2.P.2.2.1	 Submit justification of not performing tests of dissolution in Pharmaceutical equivalence studies. Comparative dissolution profile study shall be submitted against the innovator drug product. 	• Firm has submitted revised Pharmaceutical equivalence studies including dissolution test and CDP studies against the Hidrasec sachet for both 10mg & 30mg strength.
8.	3.2.P.5	Justification shall be submitted for not including dissolution test in the drug product specifications	Firm has submitted revised drug product specifications including dissolution test.
9.	3.2.P.8	 Justification shall be submitted for not performing tests of dissolution during stability studies. Documents confirming import of API shall be submitted, attested from DRAP I&E office. 	 Firm has submitted performance of recent time point of long term stability studies including performance of dissolution test. Firm has submitted readable copy of invoice No. EXP/1334 dated 19-02-2020 for import of 0.85kg of Racecadotril (Batch#2KA0261119) in name of M/s Genix Pharma (Pvt.) Ltd attested by AD (I&E) DRAP Karachi dated 17-03-2020.

Decision: Registration Board approved the applications of Dactril sachet 10mg & Dactril sachet 30mg with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for each strength for correction/pre-approval change in product specifications 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.

21.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	 ☐ Manufacturer ☐ Importer ☑ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	 □ Domestic sale □ Export sale ⋈ Domestic and Export sales

Dy.No 24846 dated 08-09-2021
Rs.75,000/- dated 14-06-2021
Dorip Injection
Each vial contains: Doripenem Monohydrate eq. to Doripenem500i
A white to slightly yellowish off-white crystal powder.
Anti-bacterial
As per innovator's specifications
1's
As per PRC
Doribax Injection by Shionogi & Co. Ltd. Ja Approved.
Dorinem Injection by M/s ICI Pakistan no: 098825
New GMP granted on 07/10/2021 Dry powder Injection (General antibiotic) approved
Kopran Research Laboratories Limited. Parijat House, Dr. E. Moses Road, Wo Mumbai-400018, India.
Firm has submitted QOS as per WHO QOS template. Summarized information related nomenclature, structure, general proper solubilities, physical form, manufacturers, descrip of manufacturing process and controls, impuring specifications, analytical procedures and verification, batch analysis and justification specification, reference standard, container clossystem and stability studies of drug substance and oproduct is submitted.
Doripenem is non-pharmacopeial. The firm submitted detail of nomenclature, structure, gen properties, solubilities, physical form, manufactur description of manufacturing process and controls, t for impurity & related substances, specificationallytical procedures and its verification, be analysis and justification of specification, refere standard, container closure system and stability stude of drug substance.
Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 60 mont Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 mont Batches: (DPIV/P1503001, DPIV/P1503002) DPIV/P1503003)
The firm has submitted detail of manufacture description of manufacturing process and contribution impurities, specifications, analytical procedure, validation studies, batch analysis and justification

			against the brand leader that is Dorinem Injection (B#0E0457) by ICI Pakistan by performing quality tests (Appearance, Identification, pH, Assay,)		
	Analytical method v product	alidation/verification of	Method validation studies including specificity, linear repeatability, intermediate prand justification of system su	rity, accuracy, precision, recision, robustness, range	
		STABILITY S	TUDY DATA		
Manu	facturer of API	Kopran research laborato	ries Ltd.		
API L	ot No.	DPIV/P1901002			
	iption of Pack ainer closure system)	Aluminium canister			
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			
Freque	ency	•	ccelerated: 3 & 6 (Months) eal Time: 3, 6, 9, 12,18 & 24 (Months)		
Batch	No.	001I050	002I050	003I050	
Batch	Size	5657 Vials	5657 Vials	5657 Vials	
Manu	facturing Date	07-2019	09-2019	11-2019	
Date of	of Initiation	19-08-2019	01-10-2019	31-12-2019	
No. of	f Batches		03		
Administrative Portion					
1.	Reference of previous with stability study data	approval of applications 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).		Copy of Purchase invoice No. BEXP-1819-384 dated 15.03.2019 is 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		Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			itted	

• The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 277th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 277th meeting on Form 5D, based on the stability data verified by On-site inspection. The details of the already considered product in 277th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek	
	Road Karachi	
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek	
	Road Karachi	
Brand Name	Ronim Injection 500mg	
Batch No. of drug product	TR001 TR002 TR003	
Case No.	900	
Registration Board	277 th meeting of Registration Board held on 27-29 th	
meeting	December, 2017	

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 277th meeting:
 - ➤ Method used for analysis of API along with COA.
 - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
 - > Record of comparative analysis against the reference product of DORIBAX Injection.
 - > Complete batch manufacturing record of three stability batches.
 - > Finished drug product analytical method validation
 - > Reports of stability studies of API from manufacturer.
 - ➤ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

- > QOS.
- Process validation protocol.
- Analytical method validation studies for drug product.

Previously the applied formulation was developed and approved with innovator's specifications, whereas subsequently it has been identified that JP monograph is now available for the "Doripenem for injection."

Decision: Approved with JP specifications. The firm shall submit fee of Rs. 7,500/- for correction/preapproval change in product specifications 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.

22.	Name, address of Applicant / Marketing Authorization Holder	M/s Wilshire Laboratories Private Limited 124/1 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.
	Name, address of Manufacturing site.	M/s Wilshire Laboratories Private Limited 124/1 Quaid-e-Azam Industrial Estate, Kot Lakhpat 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)
	Intended use of pharmaceutical product	 □ Domestic sale □ Export sale ☑ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 2386 dated 25-01-2023
	Details of fee submitted	PKR 75,000/-: dated 08-12-2022
	The proposed proprietary name / brand name	Trivesta-M XR 12.5/2.5/1000mg Tablet

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Empagliflozin (Immediate Release) 12.5mg Linagliptin (Immediate Release) 2.5mg Metformin HCl (Extended Release)1000mg
Pharmaceutical form of applied drug	Grey colored, oblong shaped Film coated Extended Release Tablet.
Pharmacotherapeutic Group of (API)	Anti-Diabetic (Type-II)
Reference to Finished product specifications	Manufacturer's Specifications
Proposed Pack size	2×7's, 4×7's, 2×5's
Proposed unit price	As per SRO
The status in reference regulatory authorities	TRIJARDY XR 12.5/2.5/1000mg Tablet by Boehringer Ingelheim International GmbH (USFDA approved)
For generic drugs (me-too status)	Not Available
GMP status of the Finished product manufacturer	New license granted on 14/09/2022 Tablet (General, Narcotics & Psychotropic) section approved.
Name and address of API manufacturer.	Empagliflozin: M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. Linagliptin: M/s Lee Pharma Limited, Survey No. 10/G-1, Gadda Potharam (Village) Jinnaram (Mandal), Sangareddy (District) Telangana, 502319, INDIA. Metformin HCl: M/S Ipca Laboratories Limited, H-4, M.LD.C., Waluj, Aurangabad (Maharashtra) Pin: 431 136, 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)	Official monographs of Empagliflozin, Linagliptin are not available in any official Pharmacopoeia & Official monograph of Metformin HCl is available in British Pharmacopoeia as well as in United States Pharmacopoeia. The API Manufacturer of Metformin HCl used B.P. Specifications & Manufacturers of Empagliflozin and Linagliptin used In-house Specifications. The firm as submitted both APIs details of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description

of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of both drug substances.				
Empagliflozin: Stability study conditions: Real time: $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$ RH for 24 months Accelerated: $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%$ RH for 6 months Batches: $(20160606, 20161017, 20161219)$ Linagliptin: Stability study conditions: Real time: $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$ RH for 36 months Accelerated: $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%$ RH for 6 months Batches: (LI0316005, LI0316006, LI0316007) Metformin HCl: Stability study conditions: Real time: $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$ RH for 60 months Accelerated: $40^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$ RH for 60 months Accelerated: $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%$ RH for 6 months Batches: (9002ML2RMI, 9003ML2RMI, 9004ML2RMI)				
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 have been established against the brand leader that is TRIJARDY XR 12.5/2.5/1000mg Tablets by Boehringer Ingelheim International GmbH by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is TRIJARDY XR 12.5/2.5/1000mg Tablet by Boehringer Ingelheim International GmbH in Acid media (0.1N HCl) & Buffer (pH 4.5 & 6.8). The values for f1 and f2 are in the acceptable range.				
verification of Method verification studies have submitted including linearity, range, accuracy, precision, specificity.				
STABILITY STUDY DATA				
Manufacturer of API Empagliflozin: M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. Linagliptin: M/s Lee Pharma Limited, Survey No. 10/G-1, Gadda Potharam (Village) Jinnaram (Mandal), Sangareddy (District) Telangana, 502319, INDIA.				
n/\dagle				

		Metformin HCl: M/S Ipca Laboratorio (Maharashtra) Pin: 431 136, India.	es Limited, H-4, M.LD.C	C., Waluj, Aurangabad	
API L	ot No.	Empagliflozin: H-E-20210826-D02-E06-01 Linagliptin: LIFP21012 Metformin HCl: 21296ML2ARMI			
	iption of Pack ainer closure system)	Alu-Alu blister packed in unit carton (2×7's)			
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.	NPD/PR22-023/T1/S1	NPD/PR22-023/T1/S2	NPD/PR22-023/T1/S3	
Batch	Size	2000 tab	2000 tab	2000 tab	
Manu	facturing Date	02-2022	02-2022	02-2022	
Date of	of Initiation	26-02-2022	26-02-2022	26-02-2022	
No. of	f Batches		03		
		Administrat	tive Portion		
	1. Reference of previous approval of applications with stability study data of the firm (if any)		The firm has also submitted per decision of 312 DRB Me all the required documents of Firm requested to please exemption from onsite inspection done on 21st Maregistration of that product varieties.	eting, they have submitted mentioned in minutes. So, e interimly extend the ection to 05 years for all abmitted required data and ay 2019 and wherein the	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			Drug Administration, L. Dis.No: RUGS CONTROL rnment of Telangana No.: NEW-WHO- 21/11/37725 issued by	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Empagliflozin: Copy of Invoice HN211026- submitted wherein the permi Empagliflozin (10Kg) for the and stability studies is grante DRAP dated 09-11-2021. Linagliptin:	ssion to import e purpose of test/analysis	

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		Copy of Invoice 1269/LP/2021-22 dated 07-10-2021 is submitted wherein the permission to import Linagliptin (4Kg) for the purpose of test/analysis and stability studies is granted vide No. 15358/2021-DRAP dated 13-10-2021. Metformin HCl: Copy of Invoice SMP2122/1630075 dated 25-08-2021 is submitted wherein the permission to import Linagliptin for the purpose of test/analysis and stability studies is granted vide No. 13246/2021-DRAP dated 02-09-2021.
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)	

Remarks of Evaluator:

Section#	Observations	Firm's response					
1.6.5	Copy of Valid GMP certificate for M/s Fuxin Long						
	Rui, issued by relevant regulatory authority shall be						
	submitted.						
Empagliflozin							
3.2.S.4	Copies of the Drug substance specifications and						
	analytical procedures used for routine testing of the						
	Drug substance /Active Pharmaceutical Ingredient by						
22542	Drug Product manufacturer is required.						
3.2.S.4.3	Analytical Method Verification studies including						
	specificity, accuracy and repeatability (method						
	precision) performed by the Drug Product						
3.2.S.4.4	manufacturer shall be submitted.						
3.2.3.4.4	Submitted COA from M/s Wilshire, mentions different batch number from that declared on the						
	COA from drug substance manufacturer. • Submitted COA from M/s Wilshire mentions test						
	Submitted COA from M/s Wilshire mentions test of "Water content" whereas COA from Drug						
	substance manufacturer specifies test of "Loss on						
	drying".						
	In contrary to the innovator drug product literature						
	from the US FDA & EMA, the section 3.2.S.1.3						
	& submitted COA of drug substance from M/s						
	Wilshire declare the solubility in water as						
	"practically insoluble". Justification shall be						
	submitted in this regard.						
	• Submitted COA of drug substance from M/s						
	Wilshire declare the results for test of optical						
	rotation which is not included in the drug						
	substance specifications and COA form drug						
	substance manufacturer.						
3.2.S.5	Submitted COA of working standard declare the						
	expiry date as 18-04-2018 whereas drug substance						
	analysis has been performed subsequent to this date.						
	Justification shall be submitted in this regard.						
Metformin HCl							

3.2.S.4	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	
3.2.8.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
3.2.8.5	Submitted COA of working standard declare the expiry date as June, 2019 whereas drug substance analysis has been performed subsequent to this date. Justification shall be submitted in this regard.	
	Linagliptin	
3.2.8.4	 Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required. Justification shall be submitted for the proposed limits of "NMT 1.0%" for the test of "Enantiomer content (S-Isomer content) by the drug substance manufacturer. As per innovator drug product literature review the "S-isomer" is controlled as an impurity. While referring to the declared limit from drug substance manufacturer for "S-Isomer", the limit for the "Total impurities" as "NMT 1.0%" shall be justified. 	
3.2.8.4.3	 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. Submitted method of analysis from drug substance manufacturer for the test of "Enantiomeric purity declares use of tests sample for both standard and sample solution. Justification shall be submitted din this regard. 	
3.2.8.4.4	 Submitted COA from M/s Wilshire mentions test of "Water content" whereas COA from Drug substance manufacturer specifies test of "Loss on drying". Submitted COA of drug substance from both drug product and drug substance manufacturer does not confirm "Enantiomeric purity". Justification shall be submitted in this regard. Submitted COA of drug substance from M/s Wilshire declare the results for test of residue on ignition which is not included in the drug substance specifications and COA form drug substance manufacturer. 	
3.2.8.5	Submitted COA of working standard of Linagliptin & S-Isomer declare the expiry date as November, 2019 & December, 2018 respectively, whereas drug substance analysis has been performed subsequent to this date. Justification shall be submitted in this regard.	
3.2.P.1	• Justification shall be submitted for proposed Quantity/tablet of Empagliflozin and Linagliptin	
3.2.P.2	 against the label claim. Justification shall be submitted for proposed quantity of Arginine in the formulation. Submit the image/picture/snapshot of the innovator/reference/comparator pack 	

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		against which Pharmaceutical equivalence / Comparative Dissolution Profile studies have been performed and
		shall reveal the details of brand name,
		manufacturer, batch# and expiry date of
		the innovator/reference/comparator
		product.
		Dissolution specifications mentioned in
		Pharmaceutical equivalence studies for
		•
Empagliflozin are different from that declared in section 3.2. P.5.1.		
		Justification shall be submitted for not
		performing tests of water content,
		uniformity of content, microbial purity
		and arginine content in Pharmaceutical
		equivalence studies as recommended by
		the innovator product literature review
		from reference regulatory authorities.
		Details shall be submitted for the
		dissolution parameters applied for the
		performance of CDP studies.
		Complete analytical record shall be
		submitted for the performance of the
		Pharmaceutical equivalence & CDP
		studies.
		The results presented for the dissolution
		profile of innovator product i.e., Trijardy
		XR tablet are contradictory to those
		reported in the review literature f
		innovator product from the reference
		regulatory authority. Justification shall be
		submitted in this regard.
-	3.2.P.3.4	In contrary to the recommendations of innovator
		product literature, "particle size" of Empagliflozin
		& Linagliptin has not been identified as Critical
-	3.2.P.5.1	Quality Attribute.
	3.2.F .3.1	Justification shall be submitted for not including tests of water content, microbial purity and
		arginine content in drug product
		specifications as recommended by the
		innovator product literature review from
		reference regulatory authorities.
-	3.2.P.5.3	Justification shall be submitted that how
		the "specificity" of the applied method
		has been inferred without the
		performance of "Peak Purity Test (e.g.,
		using diode array detector) to establish that
		analyte chromatographic peak is not attributable
		to more than one component".
		Concentrations (in mg/ml) applied for the
		performance of Linearity and Accuracy
		parameter shall be justified against the
		standard and sample concentrations of

	 each drug substance declare din the drug product analytical procedure for Assay test. Limits of 90-110% for the performance of accuracy parameter shall be justified. 	
3.2.P.5.4	The copies of complete analysis of trial batches shall be provided.	
3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	
3.2.P.8.3	 Justification shall be submitted for not including tests of water content, microbial purity and arginine content in stability studies. Peak integration and run time is not evident from the submitted chromatograms. Complete raw data sheets for the performance of Assay & Dissolution test during stability studies shall be submitted, wherein details of standard weight, sample weight, dilution preparation and calculation formula applied for the results shall have been included. Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. 	
2.3.R	 Justification shall be submitted for dispensed quantity of Empagliflozin & Linagliptin alongwith 10% overage for formulation of trial batches. Justification shall be submitted for the seal coating applied on Metformin HCl core, while referring to the innovator drug product formulation. Justification shall be submitted for proceeding for the final film coating step without establishing the content of Empagliflozin & Linagliptin at in process stage of active coating. Clarification shall be submitted for the test applied to confirm that desired content for Empagliflozin and Linagliptin has been achieved via active coating since submitted trial batch manufacturing record does not include any in process testing. Minimum handling capacity of the equipment used in the manufacturing of trial batches shall be submitted. 	

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

Agenda of Evaluator PEC-III

Case No. 03 Registration applications of Form-5 cases

a) New cases

2.	3.	Name and address of manufacturer /	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial
		Applicant	Estate, Kotlakhpat, Lahore, Pakistan
		Brand Name +Dosage Form + Strength	Obsilate Tablet 500mg

	Composition	Each Film Coated Tablet Contains:
		Calcium Dobesilate500mg
	Diary No. Date of R& I & fee	Dy No. 16077: 07-03-2019
	Dhamas alasia I Casas	PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antivaricose Therapy
	Type of Form Finished Product Specification	Form 5 Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Could not be confirmed
	Regulatory Authorities.	
	Me-too status	Could not be confirmed
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator ³ .	Evidence of approval of applied formulation in reference regulatory
	Remarks of the Evaluator.	authorities/agencies which were adopted by the Registration Board in
		its 275th meeting.Evidence of applied formulation/drug already approved by DRAP
		(generic / me-too status) along with registration number, brand name
		and name of firm
	Decision: Deferred for following:	
		rug already approved by DRAP (generic / me-too status) alongwith
	registration number, brand name a	
	Evidence of approval of applied f adopted by the Designation Record	formulation in reference regulatory authorities/agencies which were
24.	adopted by the Registration Board Name and address of manufacturer /	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial
27.	Applicant	Estate, Kotlakhpat, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Obfylin Syrup 100mg/5ml
	Composition	Each 5ml of Syrup Contains:
		Doxofylline100mg
	Diary No. Date of R& I & fee	Dy No. 16070: 07-03-2019
	Pharmacological Group	PKR 20,000/-: 07-03-2019 Other Systemic Drugs For Obstructive Airway Diseases
	Type of Form	Other Systemic Drugs For Obstructive Airway Diseases Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	AIFA Italy Approved
	Regulatory Authorities.	
	Me-too status	Unifyline Syrup by Platinum
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection
	Remarks of the Evaluator ³ .	conducted on 22-02-2022
	Decision: Approved with Innovator's s	pecifications.
	·	or revision of specifications as per notification No.F.7-11/2012-
	B&A/DRAP dated 07-05-2021.	
25.	Name and address of manufacturer /	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial
	Applicant	Estate, Kotlakhpat, Lahore, Pakistan
	Brand Name +Dosage Form + Strength Composition	Obzin Syrup 20mg/5ml Each 5ml Contains:
	Composition	Zinc (as Sulphate monohydrate)20mg
	Diary No. Date of R& I & fee	Dy No. 16078: 07-03-2019
	-	PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other Mineral Supplements
	Type of Form	Form 5
	Finished Product Specification Pack size & Demanded Price	Ph. Int.
	Approval status of product in Reference	As per SRO Could not be confirmed in any RRA or NEML, Paediatric zinc sulfate
	Regulatory Authorities.	oral solution monograph in international pharmacopoeia under the
		heading of Additional information specifies that "Available strengths:
		10 mg or 20 mg of zinc per 5 mL"
	Me-too status	Zincbar Syrup by MBL Pharma
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection
		conducted on 22-02-2022

	Remarks of the Evaluator ³ .	
	Decision: Approved.	
26.	Name and address of manufacturer /	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial
	Applicant	Estate, Kotlakhpat, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Obsemide Tablet 20mg
	Composition	Each Tablet Contains:
		Furosemide20mg
	Diary No. Date of R& I & fee	Dy No. 16075: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Uriside tablet by Nabiqasim
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection
		conducted on 22-02-2022
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
27.	Name and address of manufacturer /	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial
	Applicant	Estate, Kotlakhpat, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Obsemidel Tablet 40mg
	Composition	Each Tablet Contains:
		Furosemide40mg
	Diary No. Date of R& I & fee	Dy No. 16076: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Uriside tablet by Nabiqasim
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection
		conducted on 22-02-2022
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
28.	Name and address of manufacturer /	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial
	Applicant	Estate, Kotlakhpat, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Clazine Tablet 30mg
	Composition	Each Modified Release Tablet Contains:
		Gliclazide30mg
	Diary No. Date of R& I & fee	Dy No. 16066: 07-03-2019
	_	PKR 20,000/-: 07-03-2019
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Could not be confirmed
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Regulatory Authorities.	
	Regulatory Authorities. Me-too status	Could not be confirmed
	Regulatory Authorities.	Could not be confirmed GMP certificate issued on dated 07-03-2022 based on inspection
	Regulatory Authorities. Me-too status GMP status	Could not be confirmed GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Regulatory Authorities. Me-too status	Could not be confirmed GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022 • Evidence of approval of applied formulation in reference regulatory
	Regulatory Authorities. Me-too status GMP status	Could not be confirmed GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in
	Regulatory Authorities. Me-too status GMP status	Could not be confirmed GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Regulatory Authorities. Me-too status GMP status	Could not be confirmed GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP
	Regulatory Authorities. Me-too status GMP status	Could not be confirmed GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

Name and address of manufacturer /	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial
Applicant	Estate, Kotlakhpat, Lahore, Pakistan
Brand Name +Dosage Form + Strength	Clazine Tablet 60mg
Composition	Each Modified Release Tablet Contains:
	Gliclazide60mg
Diary No. Date of R& I & fee	Dy No. 16067: 07-03-2019
	PKR 20,000/-: 07-03-2019
Pharmacological Group	Sulfonylureas
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	Could not be confirmed
Regulatory Authorities.	
Me-too status	Could not be confirmed
GMP status	GMP certificate issued on dated 07-03-2022 based on inspection
	conducted on 22-02-2022
Remarks of the Evaluator ³ .	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm

Decision: Deferred for following:

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

Name and address of manufacturer /	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial
Applicant	Estate, Kotlakhpat, Lahore, Pakistan
Brand Name +Dosage Form + Strength	Obicetam Syrup 1g/5ml
Composition	Each 5ml of Syrup Contains:
	Piracetam1g
Diary No. Date of R& I & fee	Dy No. 16071: 07-03-2019
	PKR 20,000/-: 07-03-2019
Pharmacological Group	Other psychostimulants and nootropics
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM
Regulatory Authorities.	France Approved.
Me-too status	Nootropil Syrup by AGP
GMP status	GMP certificate issued on dated 07-03-2022 based on inspection
	conducted on 22-02-2022
Remarks of the Evaluator ³ .	

Decision: Approved with Innovator's specifications.

• 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.

31.	Name and address of manufacturer /	M/a Observa Dhammacouticala 200 C. Queid a Azem Industrial
31.	Name and address of manufacturer /	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial
	Applicant	Estate, Kotlakhpat, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Oxamin Tablet 550mg
	Composition	Each Tablet Contains:
		Rifaximin550mg
	Diary No. Date of R& I & fee	Dy No. 16080: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Axibol Tablet by Genetics Pharma
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin550mg
		ains: revision of formulation from un-coated tablet to film coated tablet as
22	per notification No.F.7-11/2012-H	
32.	Name and address of manufacturer /	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial
	Applicant	Estate, Kotlakhpat, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Obivarox Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban10mg
	Diary No. Date of R& I & fee	Dy No. 16064: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Direct factor Xa inhibitors
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Taboxa Tablet by Novamed
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator ³ . Decision: Approved.	
22	Name and address of manufacturer /	M/s Dalzhaim International Dharma Dut I td 28 Km Faraga Dur
33.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore
33.	Applicant Brand Name +Dosage Form + Strength	Road, Lahore Osteomend 70mg Tablet
33.	Applicant	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains:
33.	Applicant Brand Name +Dosage Form + Strength Composition	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg
33.	Applicant Brand Name +Dosage Form + Strength	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5 USP
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5 USP As per SRO
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5 USP
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5 USP As per SRO
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5 USP As per SRO MHRA Approved
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5 USP As per SRO MHRA Approved
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5 USP As per SRO MHRA Approved Alendra 70mg Tablet by Miracle Pharma • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Tablet Contains:
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5 USP As per SRO MHRA Approved Alendra 70mg Tablet by Miracle Pharma • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Tablet Contains: Alendronic acid (as sodium trihydrate)70mg
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labely	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5 USP As per SRO MHRA Approved Alendra 70mg Tablet by Miracle Pharma • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Tablet Contains: Alendronic acid (as sodium trihydrate)70mg
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laborated the product of the state of the state of the Each Tablet Contains:	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5 USP As per SRO MHRA Approved Alendra 70mg Tablet by Miracle Pharma • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Tablet Contains: Alendronic acid (as sodium trihydrate)70mg el claim:
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laborated acid (as sodius)	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5 USP As per SRO MHRA Approved Alendra 70mg Tablet by Miracle Pharma • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Tablet Contains: Alendronic acid (as sodium trihydrate)70mg el claim: m trihydrate)70mg
33.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labe Each Tablet Contains: Alendronic acid (as sodiu Registration letter will be issue The firm shall submit fee of Registration No.F.7-11/2	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5 USP As per SRO MHRA Approved Alendra 70mg Tablet by Miracle Pharma • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Tablet Contains: Alendronic acid (as sodium trihydrate)70mg el claim:
34.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labe Each Tablet Contains: Alendronic acid (as sodiu Registration letter will be issue The firm shall submit fee of Registration	Road, Lahore Osteomend 70mg Tablet Each Tablet Contains: Alendronate As Sodium70mg Dy No. 13656: 07-03-2019 PKR 20,000/-: 06-03-2019 Bisphosphonates Form 5 USP As per SRO MHRA Approved Alendra 70mg Tablet by Miracle Pharma • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Tablet Contains: Alendronic acid (as sodium trihydrate)70mg et claim: m trihydrate)70mg et after submission of updated GMP inspection report by the firm. s. 30,000/- for correction/pre-approval change in product label claim

	Brand Name +Dosage Form + Strength	Goutcure 80mg Tablet
	Composition	Each Tablet Contains:
		Febuxostat80mg
	Diary No. Date of R& I & fee	Dy No. 13658: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-gout Preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Zurig Tablet by Getz
	GMP status	
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
	Desiries Assessed with Issues to 22	years.
	Decision: Approved with Innovator's s	
		ed after submission of updated GMP inspection report by the firm. or revision of specifications as per notification No.F.7-11/2012-
	B&A/DRAP dated 07-05-2021.	
35.	Name and address of manufacturer /	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur
	Applicant	Road, Lahore
	Brand Name +Dosage Form + Strength	Itoride 150mg Tablet
	Composition	Each Tablet Contains:
		Itopride As HCl150mg
	Diary No. Date of R& I & fee	Dy No. 13659: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiemetics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price Approval status of product in Reference	As per SRO Could not be confirmed
	Regulatory Authorities.	
	Me-too status	Ganaton OD Tablet by Abbott
	GMP status	
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		years. • Evidence of approval of applied formulation in reference regulatory
		authorities/agencies which were adopted by the Registration Board in
		its 275th meeting.
	Decision: Deferred for evidence of appr	roval of applied formulation in reference regulatory
		ed by the Registration Board in its 275th meeting.
36.	Name and address of manufacturer /	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur
	Applicant	Road, Lahore
	Brand Name +Dosage Form + Strength	Itracone 100mg Capsule
	Composition	Each Capsule Contains:
	D'an Na Data (D.O. I.O.C.)	Itraconazole100mg
	Diary No. Date of R& I & fee	Dy No. 13661: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antimycotics For Systemic Use
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Icon Capsule by Ferozesons
	GMP status	A 11.5 y 11.5 11.5 1
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		years.
		Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).
	<u>l</u>	differential fee (in case of imported penets).

	• Revise your label claim as per the innovator's product as under along
	with submission of full fee of registration:
	Each Capsule Contains:
	Itraconazole (as IR pellets)100mg

Each Capsule Contains:

Itraconazole (as IR pellets)...100mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.
- Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.

. Name and address of manufacturer /	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur
Applicant	Road, Lahore
Brand Name +Dosage Form + Strength	Linzorin 400mg Tablet
Composition	Each Tablet Contains:
	Linezolid400mg
Diary No. Date of R& I & fee	Dy No. 13663: 07-03-2019
	PKR 20,000/-: 06-03-2019
Pharmacological Group	Other antibacterials
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	USFDA Approved
Regulatory Authorities.	
Me-too status	Nezkil Tablet by S.J&G Fazul Ellahie
GMP status	
Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following:
	Each Film Coated Tablet Contains:
	Linezolid400mg

Decision: Approved with Innovator's specifications and with following label claim:

Each Film Coated Tablet Contains:

Linezolid...400mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

38.	Name and address of manufacturer /	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur
	Applicant	Road, Lahore
	Brand Name +Dosage Form + Strength	Linzorin 600mg Tablet
	Composition	Each Tablet Contains:
		Linezolid600mg
	Diary No. Date of R& I & fee	Dy No. 13664: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antibacterials
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Nezkil Tablet by S.J&G Fazul Ellahie
	GMP status	
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
		• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following:
		Each Film Coated Tablet Contains:
		Linezolid600mg

Decision: Approved with Innovator's specifications and with following label claim:

Each Film Coated Tablet Contains:

Linezolid...600mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

. Name and address of manufacturer /	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur
Applicant	Road, Lahore
Brand Name +Dosage Form + Strength	Ondon 8mg Tablet
Composition	Each Tablet Contains:
	Ondansetron8mg
Diary No. Date of R& I & fee	Dy No. 13660: 07-03-2019
	PKR 20,000/-: 06-03-2019
Pharmacological Group	Antiemetic
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	MHRA Approved
Regulatory Authorities.	
Me-too status	Danset Tablet by CCL
GMP status	
Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
	• Revise your label claim along with submission of full fee as per the innovator's product as per following:
	Each Film Coated Tablet Contains:
	Ondansetron (as hydrochloride dihydrate)8mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:

Ondansetron (as hydrochloride dihydrate)...8mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

. Name and address of manufacturer /	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur
Applicant	Road, Lahore
Brand Name +Dosage Form + Strength	Hi-Slim 120mg Tablet
Composition	Each Tablet Contains:
	Orlistat120mg
Diary No. Date of R& I & fee	Dy No. 13665: 07-03-2019
	PKR 20,000/-: 06-03-2019
Pharmacological Group	Antiobesity
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	Could not be confirmed
Regulatory Authorities.	
Me-too status	Could not be confirmed
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three
	years.
	• Submission of source of pellets in which stability studies of the pellets
	have been conducted at real time conditions i.e., $30^{\circ}\text{C} \pm 2^{\circ}\text{C}/65\%$ RH
	\pm 5% RH along with quantification of degradation products throughout
	the stability studies / assigned shelf life.
Desigion, Deferred for followings	

Decision: Deferred for following:

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

41.	Name and address of manufacturer /	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur
	Applicant	Road, Lahore

Brand Name +Dosage Form + Strength	Tamlusin 0.4mg Capsule
Composition	Each Capsule Contains:
	Tamsulosin Hcl Sustained Release Pellets Eq. To Tamsulosin
	Hcl0.4mg
Diary No. Date of R& I & fee	Dy No. 13655: 07-03-2019
	PKR 20,000/-: 06-03-2019
Pharmacological Group	Alpha-adrenoreceptor antagonists
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	MHRA Approved
Regulatory Authorities.	
Me-too status	Maxflow Capsule by CCL
GMP status	
Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
	years.
	• Provide source of pellets along with COA, stability study data of 3
	batches of pellets, GMP certificate of pellets manufacturer and
	differential fee (in case of imported pellets).
	Revise your label claim as per the innovator's product as under along
	with submission of full fee of registration:
	Each Capsule Contains:
	Tamsulosin HCl Modified Release Pellets Eq To
	Tamsulosin0.4mg

Each Capsule Contains:

Tamsulosin HCl Modified Release Pellets Eq To Tamsulosin.....0.4mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.
- Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.

 Name and address of manufacturer / M/s Paramount Pharmaceuticals Plot No. 36. Industrial Triangle.

42.	Name and address of manufacturer /	M/s Paramount Pharmaceuticals Plot No. 36, Industrial Triangle,
	Applicant	Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Seta Tablet 8mg
	Composition	Each Tablet Contains:
		Betahistine Dihydrochloride8mg
	Diary No. Date of R& I & fee	Dy No. 16299: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Serc Tablet by Abbott
	GMP status	GMP certificate dated 27-07-2021 issued on the basis
		of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
43.	Name and address of manufacturer /	M/s Paramount Pharmaceuticals Plot No. 36, Industrial Triangle,
	Applicant	Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Seta Tablet 16mg
	Composition	Each Tablet Contains:
		Betahistine Dihydrochloride16mg
	Diary No. Date of R& I & fee	Dy No. 16296: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Serc Tablet by Abbott
	GMP status	GMP certificate dated 27-07-2021 issued on the basis
		of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
44.	Name and address of manufacturer /	M/s Paramount Pharmaceuticals Plot No. 36, Industrial Triangle,
	Applicant	Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Seta Tablet 24mg
	Composition	Each Tablet Contains:
		Betahistine Dihydrochloride24mg
	Diary No. Date of R& I & fee	Dy No. 16297: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	Como Tohlat by: Abbatt
	Me-too status GMP status	Serc Tablet by Abbott GMP certificate dated 27-07-2021 issued on the basis
	GWP status	
	Description of the Early 13	of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator ³ .	
45.	Decision: Approved. Name and address of manufacturer /	M/s Donomount Dhamma continues Diet No. 26 Industrial Triangle
45.	Applicant	M/s Paramount Pharmaceuticals Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Quetil Tablet 25mg
	Composition	Each Tablet Contains:
	Disa No Data (D. 1.0.C)	Quetiapine Fumarate25mg
	Diary No. Date of R& I & fee	Dy No. 16294: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	11
	Me-too status	Q-Par Tablet by Helix
	GMP status	GMP certificate dated 27-07-2021 issued on the basis
		of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator ³ .	 Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Quetiapine (as fumarate)25mg
	Decision: Approved with following laborates	
	Each Film Coated Tablet	
	Quetiapine (as fumarate)	
		s. 30,000/- for correction/pre-approval change in product label claim
		012-B&A/DRAP dated 07-05-2021, before issuance of registration
	letter.	
46.	Name and address of manufacturer / Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, KPK
	Brand Name +Dosage Form + Strength	Deslor 0.5mg/ml Syrup
	Composition	Each 5ml Syrup Contains:
	District CD0 10 C	Desloratadine2.5mg
	Diary No. Date of R& I & fee	Dy No. 16180: 07-03-2019
	Pharmacological Group	PKR 20,000/-: 06-03-2019 Other antihistamines for systemic use
	Pharmacological Group	Form 5
<u></u>	Type of Form	TOTH J

Finished Product Specification	Firm has claimed in house specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	MHRA Approved
Regulatory Authorities.	
Me-too status	Dezika Syrup by Islam Pharma
GMP status	
Remarks of the Evaluator ³ .	

Decision: Approved with Innovator's specifications.

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

. Name and address of manufacturer /	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial
Applicant	Estate Gadoon, Sawabi, KPK
Brand Name +Dosage Form + Strength	Deslor 5mg Tablet
Composition	Each Film Coated Tablet Contains:
	Desloratadine5mg
Diary No. Date of R& I & fee	Dy No. 16179: 07-03-2019
	PKR 20,000/-: 06-03-2019
Pharmacological Group	Other antihistamines for systemic use
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	USFDA Approved
Regulatory Authorities.	
Me-too status	Destina Tablet by Hilton
GMP status	
Remarks of the Evaluator ³ .	

Decision: Approved.

Registration letter will be issued after submission of updated GMP inspection report by the firm.

48.	Name and address of manufacturer / M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industri		
70.	Applicant	Estate Gadoon, Sawabi, KPK	
	Brand Name +Dosage Form + Strength	Articerin 50mg Capsule	
	Composition	Each Capsule Contains:	
		Diacerein50mg	
	Diary No. Date of R& I & fee	Dy No. 16181: 07-03-2019	
		PKR 20,000/-: 06-03-2019	
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, non-steroids	
	Type of Form	Form 5	
	Finished Product Specification	Firm has claimed in-house specifications	
	Pack size & Demanded Price	As per SRO	
	Approval status of product in Reference	Diacerein Biogaran 50 mg, capsule ANSM Approved.	
	Regulatory Authorities.		
	Me-too status	Diora Capsule by Getz	
	GMP status		
	Remarks of the Evaluator ³ .		
l	TO 1.1 A T 1.1 T	• 60	

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

49.	Name and address of manufacturer /	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial
	Applicant	Estate Gadoon, Sawabi, KPK
	Brand Name +Dosage Form + Strength	Thiosid 4mg Capsule
	Composition	Each Capsule Contains:
		Thiocolchicoside4mg
	Diary No. Date of R& I & fee	Dy No. 16178: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MIOREL 4 mg, capsule ANSM France Approved
	Me-too status	Thiolax Capsule by S.J&G Fazul Ellahie
	GMP status	Through Cupsule by Blace Fuzur Zhune
	Remarks of the Evaluator ³ .	
	Decision: Approved with Innovator's s	
		<u>-</u>
		ed after submission of updated GMP inspection report by the firm.
	• Firm shall submit 7,500/- fee fo B&A/DRAP dated 07-05-2021.	or revision of specifications as per notification No.F.7-11/2012-
50.	Name and address of manufacturer /	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Cordium V Tablets 5/80mg
	Composition	Each Film Coated Tablet Contains:
		Amlodipine as Besylate5mg
	Di N D GD G Y G G	Valsartan80mg
	Diary No. Date of R& I & fee	Dy No. 13626: 07-03-2019
	D	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Exforge Tablet by Novartis
	GMP status	GMP certificate dated 27-07-2021 issued on the basis
		of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
51.	Name and address of manufacturer /	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	C Vit Tablet 500mg
	Composition	Each Chewable Tablet Contains:
		Ascorbic Acid500mg
	Diary No. Date of R& I & fee	Dy No. 16342: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antioxidant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Could not be confirmed
	Regulatory Authorities.	
	Me-too status	Kinuca Chewable 500mg Tablet by Winthrox
	GMP status	GMP certificate dated 27-07-2021 issued on the basis
		of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator ³ .	Evidence of approval of applied formulation in reference regulatory
		authorities/agencies which were adopted by the Registration Board in
		its 275th meeting.
	Decision: Deferred for evidence of appr	roval of applied formulation in reference regulatory
		ed by the Registration Board in its 275th meeting.
52.	Name and address of manufacturer /	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Urifin Tablet 40mg
	Composition	Each Film Coated Tablet Contains:
		Febuxostat40mg
	Diary No. Date of R& I & fee	Dy No. 13627: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-gout Preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
		: =

	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Zurig Tablet by Getz
	GMP status	GMP certificate dated 27-07-2021 issued on the basis
	Givii status	of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator ³ .	
	Decision: Approved with Innovator's s	pecifications.
		for revision of specifications as per notification No.F.7-11/2012-
	B&A/DRAP dated 07-05-202	· · · · · · · · · · · · · · · · · · ·
53.	Name and address of manufacturer /	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Urifin Tablet 80mg
	Composition	Each Film Coated Tablet Contains:
	Diam, No. Data of D & I & foo	Febuxostat80mg Dy No. 13628: 07-03-2019
	Diary No. Date of R& I & fee	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-gout Preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Zurig Tablet by Getz
	GMP status	GMP certificate dated 27-07-2021 issued on the basis
		of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator ³ .	
	Decision: Approved with Innovator's s	
	• Firm shall submit 7,500/- fee B&A/DRAP dated 07-05-202	for revision of specifications as per notification No.F.7-11/2012-
54.	Name and address of manufacturer /	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road,
24.	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Onset Syrup 4mg/5ml
	Composition	Each 5ml Contains:
		Ondansetron Hcl Dihydrate Eq To Ondanserton4mg
	Diary No. Date of R& I & fee	Dy No. 16340: 07-03-2019
	Pharmacological Group	PKR 20,000/-: 07-03-2019
		Antiemetic Form 5
	Type of Form Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	minut rippioved
	Me-too status	Ondasave oral solution by Medisave
	GMP status	GMP certificate dated 27-07-2021 issued on the basis
		of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
55.	Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength Composition	Ripzole Tablet 10mg Each Tablet Contains:
	Composition	Aripiprazole10mg
	Diary No. Date of R& I & fee	Dy No. 16091: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	Ariana Tablesha Clabal
	Me-too status	Aripaze Tablet by Global

	GMP status			
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three		
		 years. Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Capsule Contains: 		
		Each Film Coated Tablet Contains: Aripiprazole10mg		
	Decision: Approved with following laboration			
	Each Film Coated Tablet Cont			
	Aripiprazole10mg			
		 Registration letter will be issued after submission of updated GMP inspection report by the firm. Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as 		
	per notification No.F.7-11/2012-Bo			
6.	Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,		
U.	Applicant	Lahore		
	Brand Name +Dosage Form + Strength	Recloza 5mg Tablet		
	Composition	Each Film Coated Tablet Contains:		
		Cyclobenzaprine HCl5mg		
	Diary No. Date of R& I & fee	Dy No. 16102: 07-03-2019		
	*	PKR 20,000/-: 07-03-2019		
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents		
	Type of Form	Form 5		
	Finished Product Specification	USP		
	Pack size & Demanded Price	As per SRO		
	Approval status of product in Reference Regulatory Authorities.	FLEXERIL (5mg, 10mg) film coated tablets USFDA Approved and Discontinued with reason that "Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons"		
	Me-too status	Cybem Tablet by Sami Pharma		
	GMP status	Cybem rubiet by built ruminu		
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last thre years.		
	Decision: Approved.	youth		
	• Registration letter will be issued after submission of updated GMP inspection report by the firm.			
7.	Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,		
	Applicant	Lahore		
	Brand Name +Dosage Form + Strength	Restero 10mg Tablets		
	2	E		

	Registration letter will be issue	ed after submission of updated GMP inspection report by the firm.
57.	Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Restero 10mg Tablets
	Composition	Each Film Coated Tablet Contains:
		Dydrogesterone10mg
	Diary No. Date of R& I & fee	Dy No. 16104: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Progestogens
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Duphaston 10mg film-coated tablets by M/s Mylan IRE
	Regulatory Authorities.	Healthcare Limited (Ireland Approved)
	Me-too status	Dydrstone 10mg Tablet by Pharmasol
	GMP status	
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		years.
		• Evidence of required manufacturing facility / section from Licensing Division
		• Clarification about the type of isomer of Dydrogesterone that will be used in formulation

Decision: Deferred for following submissions:

- Evidence of required manufacturing facility / section from Licensing Division
- Clarification about the type of isomer of Dydrogesterone that will be used in formulation
- Latest GMP inspection report conducted within a period of last three years.

Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,
Applicant	Lahore
Brand Name +Dosage Form + Strength	Rasta 10/10 mg Tablet
Composition	Each Film Coated Tablet Contains:
	Ezetimibe10mg
	Simvastatin10mg
Diary No. Date of R& I & fee	Dy No. 16098: 07-03-2019
	PKR 20,000/-: 07-03-2019
Pharmacological Group	HMG CoA reductase inhibitors in combination with other
	lipid modifying agents
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	USFDA Approved
Regulatory Authorities.	
Me-too status	Simvax Plus Tablet by Evolution pharma
GMP status	
Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three years.
	• Revise your label claim along with submission of 7500 fee as per the
	innovator's product as per following:
	Each Tablet Contains:
	Ezetimibe10mg
	Simvastatin10mg

Decision: Approved with Innovator's specifications and with following label claim:

Each Tablet Contains:

Ezetimibe...10mg

Simvastatin...10mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to un-coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,
Applicant	Lahore
Brand Name +Dosage Form + Strength	Repride 50mg Tablet
Composition	Each Film Coated Tablet Contains:
	Itopride Hcl50mg
Diary No. Date of R& I & fee	Dy No. 16092: 07-03-2019
	PKR 20,000/-: 07-03-2019
Pharmacological Group	Antiemetics
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	PMDA Japan Approved
Regulatory Authorities.	
Me-too status	Ganaton Tablet by Abbott
GMP status	
Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three
	years.
D	* 0* 1*

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

60.	Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Ramine 25mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Lamotrigine25mg
	Diary No. Date of R& I & fee	Dy No. 16106: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5

Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	MHRA Approved
Regulatory Authorities.	
Me-too status	Lamictal Tablet by GSK
GMP status	
Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three Logorer Logorer
	years.
	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following:
	Each Tablet Contains:
	Lamotrigine25mg

Each Tablet Contains:

Lamotrigine...25mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to un-coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

61.	Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Ramine 50mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Lamotrigine50mg
	Diary No. Date of R& I & fee	Dy No. 16107: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Lamictal Tablet by GSK
	GMP status	
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
		• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following:
		Each Tablet Contains:
		Lamotrigine50mg

Decision: Approved with following label claim:

Each Tablet Contains: Lamotrigine...50mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to un-coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

62.	Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Rantin 10mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Memantine As Hcl10mg
	Diary No. Date of R& I & fee	Dy No. 16087: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other anti-dementia drugs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Afdol Tablet by AGP
	GMP status	

Remarks of the Evaluator ³ .	•	Latest GMP inspection report conducted within a period of last three
		years.
	•	Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each Tablet Contains:
		Memantine HCl 10mg

Each Tablet Contains:

Memantine HCl...10mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,
Applicant	Lahore
Brand Name +Dosage Form + Strength	Rebol 10mg Tablet
Composition	Each Tablet Contains:
	Nebivolol as HCl10mg
Diary No. Date of R& I & fee	Dy No. 16090: 07-03-2019
	PKR 20,000/-: 07-03-2019
Pharmacological Group	Beta blocking agents, selective
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	MHRA Approved
Regulatory Authorities.	
Me-too status	Nebil Tablet by Getz
GMP status	
Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
	years.

Decision: Approved with Innovator's specifications.

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

64.	Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Reprazo 20mg Tablet
	Composition	Each Enteric Coated Tablet Contains:
		Rabeprazole Sodium20mg
	Diary No. Date of R& I & fee	Dy No. 16100: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Protorib Tablet by Helix
	GMP status	
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three
		years.

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

65.	Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Relsar 20mg Tablet
	Composition	Each Tablet Contains:
		Telmisartan20mg
	Diary No. Date of R& I & fee	Dy No. 16093: 07-03-2019

		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	типка арриочен
	Me-too status	Telsan Tablet by Hilton
	GMP status	Tolsair Tublet by Tillion
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
	Remarks of the Evaluator .	years.
	Decision: Approved.	years.
		ed after submission of updated GMP inspection report by the firm.
66.	Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Relsar Tablet 40mg
	Composition	Each Tablet Contains:
	_	Telmisartan40mg
	Diary No. Date of R& I & fee	Dy No. 16095: 07-03-2019
	-	PKR 20,000/-: 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Telsan Tablet by Hilton
	GMP status	
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		years.
	Decision: Approved.	
	l	
(7		ed after submission of updated GMP inspection report by the firm.
67.	Name and address of manufacturer /	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate,
67.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet
67.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains:
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs)
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved Telsan Tablet by Hilton
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved Telsan Tablet by Hilton • Latest GMP inspection report conducted within a period of last three
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved Telsan Tablet by Hilton
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved Telsan Tablet by Hilton • Latest GMP inspection report conducted within a period of last three years.
67.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved Telsan Tablet by Hilton • Latest GMP inspection report conducted within a period of last three years. ed after submission of updated GMP inspection report by the firm. M/s Rakaposhi Pharmaceuticals Pvt Ltd.
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Registration letter will be issue Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved Telsan Tablet by Hilton • Latest GMP inspection report conducted within a period of last three years. ed after submission of updated GMP inspection report by the firm. M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Registration letter will be issue Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved Telsan Tablet by Hilton • Latest GMP inspection report conducted within a period of last three years. ed after submission of updated GMP inspection report by the firm. M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan Amlosar 5/80mg Tablet
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Registration letter will be issue Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved Telsan Tablet by Hilton • Latest GMP inspection report conducted within a period of last three years. ed after submission of updated GMP inspection report by the firm. M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan Amlosar 5/80mg Tablet Each Film Coated Tablet Contains:
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Registration letter will be issue Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved Telsan Tablet by Hilton • Latest GMP inspection report conducted within a period of last three years. ed after submission of updated GMP inspection report by the firm. M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan Amlosar 5/80mg Tablet Each Film Coated Tablet Contains: Amlodipine as Besylate5mg
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Registration letter will be issue Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved Telsan Tablet by Hilton • Latest GMP inspection report conducted within a period of last three years. ed after submission of updated GMP inspection report by the firm. M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan Amlosar 5/80mg Tablet Each Film Coated Tablet Contains: Amlodipine as Besylate5mg Valsartan80mg
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Registration letter will be issue Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved Telsan Tablet by Hilton • Latest GMP inspection report conducted within a period of last three years. ed after submission of updated GMP inspection report by the firm. M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan Amlosar 5/80mg Tablet Each Film Coated Tablet Contains: Amlodipine as Besylate5mg Valsartan80mg Dy No. 16256: 07-03-2019
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. • Registration letter will be issue Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved Telsan Tablet by Hilton • Latest GMP inspection report conducted within a period of last three years. ed after submission of updated GMP inspection report by the firm. M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan Amlosar 5/80mg Tablet Each Film Coated Tablet Contains: Amlodipine as Besylate5mg Valsartan80mg Dy No. 16256: 07-03-2019 PKR 20,000/-: 06-03-2019
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Registration letter will be issue Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore Relsar 80mg Tablet Each Tablet Contains: Telmisartan80mg Dy No. 16096: 07-03-2019 PKR 20,000/-: 07-03-2019 Angiotensin II receptor blockers (ARBs) Form 5 USP As per SRO MHRA Approved Telsan Tablet by Hilton • Latest GMP inspection report conducted within a period of last three years. ed after submission of updated GMP inspection report by the firm. M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan Amlosar 5/80mg Tablet Each Film Coated Tablet Contains: Amlodipine as Besylate5mg Valsartan80mg Dy No. 16256: 07-03-2019

USP
As per SRO
MHRA Approved
Exforge Tablet by Novartis
• Latest GMP inspection report conducted within a period of last three years.

Decision: Approved.

· Registration letter will be issued after submission of updated GMP inspection report by the firm.

	Ü	ed after submission of updated GMP inspection report by the firm.
69.	Name and address of manufacturer /	M/s Rakaposhi Pharmaceuticals Pvt Ltd.
	Applicant	97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Duloxine 30mg Capsule
	Composition	Each Capsule Contains:
		Duloxetine as HC130mg
	Diary No. Date of R& I & fee	Dy No. 16253: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Dulan Capsule by Hilton
	GMP status	
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		years.
		• Provide source of pellets along with COA, stability study data of 3
		batches of pellets, GMP certificate of pellets manufacturer and
		differential fee (in case of imported pellets).
		Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each Capsule Contains:
		Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine30mg

Decision: Approved with following label claim:

Each Capsule Contains:

Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine...30mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.
- Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.

70.	Name and address of manufacturer /	M/s Rakaposhi Pharmaceuticals Pvt Ltd.
	Applicant	97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Duloxine 60mg Capsule
	Composition	Each Capsule Contains:
		Duloxetine as HCl Enteric Coated Pellets60mg
	Diary No. Date of R& I & fee	Dy No. 16243: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Dulan Capsule by Hilton
	GMP status	
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three
		years.

- Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).
- Revise your label claim along with submission of full fee as per the innovator's product as per following:
 Each Capsule Contains:
 Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine...60mg

Each Capsule Contains:

Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine...60mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.
- Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.

	255 04-04-10-10-10-10-10-10-10-10-10-10-10-10-10-	
71.	Name and address of manufacturer /	M/s Rakaposhi Pharmaceuticals Pvt Ltd.
	Applicant	97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Racoxib 60mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Etoricoxib60mg
	Diary No. Date of R& I & fee	Dy No. 16250: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiinflammatory and Antirheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Etoxib Tablet by Hiranis
	GMP status	
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		years.

Decision: Approved with Innovator's specifications.

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
Ropride 50mg Tablet
Each Film Coated Tablet Contains:
Itopride HCl50mg
Dy No. 16252: 07-03-2019
PKR 20,000/-: 06-03-2019
Antiemetics
Form 5
Firm has claimed in-house specifications
As per SRO
PMDA Japan Approved
Ganaton Tablet by Abbott
• Latest GMP inspection report conducted within a period of last three
years.

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

73	3.	Name and address of manufacturer /	M/s Rakaposhi Pharmaceuticals Pvt Ltd.
		Applicant	97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan

	Brand Name +Dosage Form + Strength	Rasomide 50mg Tablet
		Ŭ
	Composition	Each Film Coated Tablet Contains:
		Lacosamide50mg
	Diary No. Date of R& I & fee	Dy No. 16245: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	Time Trippio vou
	Me-too status	Lacolep tablet by Hilton
	GMP status	Lacorep tablet by Tinton
		Y - COMPLETE TO THE STATE OF TH
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three
		years.
	Decision: Approved.	
		ed after submission of updated GMP inspection report by the firm.
74.	Name and address of manufacturer /	M/s Rakaposhi Pharmaceuticals Pvt Ltd.
	Applicant	97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Rasomide 100mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Lacosamide100mg
	Diary No. Date of R& I & fee	Dy No. 16246: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	Y 1 . 11 . 1 YY'1.
	Me-too status	Lacolep tablet by Hilton
	GMP status	
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		years.
	Decision: Approved.	
	Registration letter will be issue	ed after submission of updated GMP inspection report by the firm.
75.	Name and address of manufacturer /	M/s Rakaposhi Pharmaceuticals Pvt Ltd.
	Applicant	97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Zapitine Capsule 6/25mg
	Composition	Each Capsule Contains:
		Olanzapine6mg
		Fluoxetine As Hcl25mg
	Diary No. Date of R& I & fee	Dy No. 16249: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Atypical antipsychotic and a selective serotonin
		reuptake inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	Deflere consula ha mania 1
	Me-too status	Byflanz capsule by martin dow
	GMP status	
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		years.
	Decision: Approved.	
	Registration letter will be issue	ed after submission of updated GMP inspection report by the firm.
76.	Name and address of manufacturer /	M/s Rakaposhi Pharmaceuticals Pvt Ltd.
	Applicant	97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Lipformin 50/500mg Tablet
1		Each Film Coated Tablet Contains:
	Composition	Lacii Tiiii Coatcu Taoici Contains.

	Sitagliptin as Phospate Monohydrate50mg
	Metformin HCl500mg
Diary No. Date of R& I & fee	Dy No. 16248: 07-03-2019
	PKR 20,000/-: 06-03-2019
Pharmacological Group	Antidiabetic
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	USFDA Approved
Regulatory Authorities.	
Me-too status	Treivamet Tablet by Getz
GMP status	
Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three
	years.

Decision: Approved with Innovator's specifications.

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

77.	Name and address of manufacturer /	M/s Rakaposhi Pharmaceuticals Pvt Ltd.
	Applicant	97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Fenarcin 5mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Solifenacin Succinate5mg
	Diary No. Date of R& I & fee	Dy No. 16258: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Solif Tablet by Global
	GMP status	
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three
		years.

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

78.	Name and address of manufacturer /	M/s Regal Pharmaceuticals Plot # 2A St.# S-5, National Industrial
	Applicant	Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Omex 40mg Capsule
	Composition	Each Capsule Contains:
		Omeprazole40mg
	Diary No. Date of R& I & fee	Dy No. 15078: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Risek capsule by Getz
	GMP status	
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
		Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). Provide source label claim along with submission of full fee as per the
		• Revise your label claim along with submission of full fee as per the innovator's product as per following:

	Each Capsule Contains:
	Omeprazole (as enteric coated pellets)40mg

Each Capsule Contains:

Omeprazole (as enteric coated pellets)...40mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.
- Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.

Name and address of manufacturer /	M/s Relizon Pharmaceuticals Plot No. 118, Sunder Industrial
Applicant	Estate, Raiwind Road, Lahore
Brand Name +Dosage Form + Strength	Reldic 100mg Tablet
Composition	Each Tablet Contains:
	Diclofenac Sodium100mg
Diary No. Date of R& I & fee	Dy No. 15503: 07-03-2019
	PKR 20,000/-: 07-03-2019
Pharmacological Group	NSAID
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	USFDA Approved
Regulatory Authorities.	
Me-too status	Diclomax SR Tablet by Quaper Pharma
GMP status	Firm has submitted copy of GMP inspection report Conducted on
	07-06-2022 which concluded as "Keeping in the View of the
	Observations made on the day of inspection and after going
	through the documentations and overall operations, the panel was
	of the opinion that the firm
	was GMP compliant on the day of inspection.
Remarks of the Evaluator ³ .	Revise your label claim along with submission of full fee as per the
	innovator's product as per following:
	Each Extended Release Tablet Contains:
	Diclofenac Sodium100mg
	1 1 *

Decision: Approved with following label claim:

Each Extended Release Tablet Contains:

Diclofenac Sodium...100mg

• The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

80.	Name and address of manufacturer /	M/s Relizon Pharmaceuticals Plot No. 118, Sunder Industrial
	Applicant	Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Ebastizon Tablet 10mg
	Composition	Each Film Coated Tablet Contains:
		Ebastine10mg
	Diary No. Date of R& I & fee	Dy No. 15500: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification while monograph is available
		in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Netherland Approved.
	Regulatory Authorities.	
	Me-too status	Kestine Tablet by Highnoon
	GMP status	Firm has submitted copy of GMP inspection report Conducted on
		07-06-2022 which concluded as "Keeping in the View of the
		Observations made on the day of inspection and after going
		through the documentations and overall operations, the panel was

of the opinion that the firm was GMP compliant on the day of inspection. Remarks of the Evaluator ³ . Decision: Approved with JP specifications. 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. 81. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition M/s Relizon Pharmaceuticals Plot No. 118, Sunder Industrial Estate, Raiwind Road, Lahore Brand Name +Dosage Form + Strength Composition Each Film Coated Tablet Contains:	
Remarks of the Evaluator ³ . Decision: Approved with JP specifications. 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. 81. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength M/s Relizon Pharmaceuticals Plot No. 118, Sunder Industrial Estate, Raiwind Road, Lahore Brand Name +Dosage Form + Strength Metrozone Tablet 400mg	
Decision: Approved with JP specifications. • 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. 81. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength M/s Relizon Pharmaceuticals Plot No. 118, Sunder Industrial Estate, Raiwind Road, Lahore Brand Name +Dosage Form + Strength Metrozone Tablet 400mg	
 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. Name and address of manufacturer / Applicant	
ApplicantEstate, Raiwind Road, LahoreBrand Name +Dosage Form + StrengthMetrozone Tablet 400mg	
Brand Name +Dosage Form + Strength Metrozone Tablet 400mg	
Metronidazole400mg	
Diary No. Date of R& I & fee Dy No. 15501: 07-03-2019	
PKR 20,000/-: 07-03-2019	
Pharmacological Group Imidazole derivatives	
Type of Form Form 5	
Finished Product Specification USP	
Pack size & Demanded Price As per SRO	
Approval status of product in Reference Regulatory Authorities. MHRA Approved	
Me-too status Flagyl Tablet by Sanofi Aventis	,
GMP status Firm has submitted copy of GMP inspection report Conduct 07-06-2022 which concluded as "Keeping in the View of th	
Observations made on the day of inspection and after going	<i></i>
through the documentations and overall operations, the pane	1 was
of the opinion that the firm	i was
was GMP compliant on the day of inspection.	
Remarks of the Evaluator ³ .	
Decision: Approved.	
82. Name and address of manufacturer / M/s Remington Pharmaceuticals Industries Pvt Ltd.	
Applicant 18 km, Multan Road, Lahore.	
Brand Name +Dosage Form + Strength Pedigerm Oral Suspension	
Composition Each 5ml Contains: Bacillus Clausii2 Billion	
Diary No. Date of R& I & fee Dy No. 16456: 07-03-2019 PKR 20,000/-: 07-03-2019	
Pharmacological Group Probiotics	
Type of Form Form 5	
Finished Product Specification Firm has claimed in-house specifications	
Pack size & Demanded Price As per SRO	
Approval status of product in Reference Could not be confirmed	
Regulatory Authorities.	
Me-too status Enterogermina oral suspension by Sanofi Aventis	
GMP status GMP inspection report dated 30th Sep 2021 and panel	
recommends considering the firm for grant of cGMP	
certificate in respect of all manufacturing sections.	
Remarks of the Evaluator ³ . • Evidence of approval of applied formulation in reference regulat	d in
Remarks of the Evaluator ³ . • Evidence of approval of applied formulation in reference regulat authorities/agencies which were adopted by the Registration Boa	
Remarks of the Evaluator ³ . • Evidence of approval of applied formulation in reference regulate authorities/agencies which were adopted by the Registration Boat its 275th meeting.	
Remarks of the Evaluator ³ . • Evidence of approval of applied formulation in reference regulat authorities/agencies which were adopted by the Registration Boa its 275th meeting. • The applied product is a probiotic, which is defined as health and	OTC
Remarks of the Evaluator ³ . • Evidence of approval of applied formulation in reference regulat authorities/agencies which were adopted by the Registration Boa its 275th meeting. • The applied product is a probiotic, which is defined as health and Products (non-drugs) as per DRAP Act 2012 and also defined under the product of the Evaluator of	OTC der
Remarks of the Evaluator ³ . • Evidence of approval of applied formulation in reference regulat authorities/agencies which were adopted by the Registration Boa its 275th meeting. • The applied product is a probiotic, which is defined as health and Products (non-drugs) as per DRAP Act 2012 and also defined un S.R.O. 412(I)/2014 while you have applied as a pharmaceutical of	OTC der
Remarks of the Evaluator ³ . • Evidence of approval of applied formulation in reference regulat authorities/agencies which were adopted by the Registration Boa its 275th meeting. • The applied product is a probiotic, which is defined as health and Products (non-drugs) as per DRAP Act 2012 and also defined un S.R.O. 412(I)/2014 while you have applied as a pharmaceutical oproduct. Clarification is required in this regard. Decision: Registration Board decided to reject the application since the applied product is a probiotic is defined as health and OTC Products (non-drugs) as per DRAP Act 2012 and also defined under S.R.	OTC der rug
Remarks of the Evaluator ³ . • Evidence of approval of applied formulation in reference regulat authorities/agencies which were adopted by the Registration Boa its 275th meeting. • The applied product is a probiotic, which is defined as health and Products (non-drugs) as per DRAP Act 2012 and also defined un S.R.O. 412(I)/2014 while you have applied as a pharmaceutical oproduct. Clarification is required in this regard. Decision: Registration Board decided to reject the application since the applied product is a probiotic is defined as health and OTC Products (non-drugs) as per DRAP Act 2012 and also defined under S.R. 412(I)/2014.	OTC der rug
Remarks of the Evaluator ³ . • Evidence of approval of applied formulation in reference regulat authorities/agencies which were adopted by the Registration Boa its 275th meeting. • The applied product is a probiotic, which is defined as health and Products (non-drugs) as per DRAP Act 2012 and also defined un S.R.O. 412(I)/2014 while you have applied as a pharmaceutical or product. Clarification is required in this regard. Decision: Registration Board decided to reject the application since the applied product is a probiotic is defined as health and OTC Products (non-drugs) as per DRAP Act 2012 and also defined under S.R. 412(I)/2014. 83. Name and address of manufacturer / M/s Remington Pharmaceuticals Industries Pvt Ltd.	OTC der rug
Remarks of the Evaluator ³ . • Evidence of approval of applied formulation in reference regulat authorities/agencies which were adopted by the Registration Boaits 275th meeting. • The applied product is a probiotic, which is defined as health and Products (non-drugs) as per DRAP Act 2012 and also defined un S.R.O. 412(I)/2014 while you have applied as a pharmaceutical oproduct. Clarification is required in this regard. Decision: Registration Board decided to reject the application since the applied product is a probiotic is defined as health and OTC Products (non-drugs) as per DRAP Act 2012 and also defined under S.R. 412(I)/2014. 83. Name and address of manufacturer / Applicant M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore.	OTC der rug
Remarks of the Evaluator ³ . • Evidence of approval of applied formulation in reference regulat authorities/agencies which were adopted by the Registration Boar its 275th meeting. • The applied product is a probiotic, which is defined as health and Products (non-drugs) as per DRAP Act 2012 and also defined un S.R.O. 412(I)/2014 while you have applied as a pharmaceutical of product. Clarification is required in this regard. Decision: Registration Board decided to reject the application since the applied product is a probiotic is defined as health and OTC Products (non-drugs) as per DRAP Act 2012 and also defined under S.R. 412(I)/2014. 83. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore. Zinstill Syrup	OTC der rug
Remarks of the Evaluator ³ . • Evidence of approval of applied formulation in reference regulat authorities/agencies which were adopted by the Registration Boar its 275th meeting. • The applied product is a probiotic, which is defined as health and Products (non-drugs) as per DRAP Act 2012 and also defined un S.R.O. 412(I)/2014 while you have applied as a pharmaceutical oproduct. Clarification is required in this regard. Decision: Registration Board decided to reject the application since the applied product is a probiotic is defined as health and OTC Products (non-drugs) as per DRAP Act 2012 and also defined under S.R. 412(I)/2014. 83. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore. Zinstill Syrup	OTC der rug

	PKR 20,000/-: 07-03-2019
Pharmacological Group	Other Mineral Supplements
Type of Form	Form 5
Finished Product Specification	Ph. Int.
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in any RRA or NEML, Paediatric zinc sulfate oral solution monograph in international pharmacopoeia under the heading of Additional information specifies that "Available strengths: 10 mg or 20 mg of zinc per 5 mL"
Me-too status	Zincbar Syrup by MBL Pharma
GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.
Remarks of the Evaluator ³ .	 Evidence of required manufacturing facility / section approval letter from Licensing Division. Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains: Zinc (as Sulphate monohydrate)20mg
Decision: Approved with following lab	
Each 5ml Contains:	

Zinc (as Sulphate monohydrate)...20mg

• The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

84.	Name and address of manufacturer / Applicant	M/s Searle IV Solutions Pvt Ltd 1.5 km, Manga Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Levoxin Opthalmic Solution
	Composition	Each ml Contains:
	_	Levofloxacin Hemihydrate Eq. To Levofloxacin15mg
	Diary No. Date of R& I & fee	Dy No. 14053: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications while monograph is available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Lequix Eye Drops by Schazoo
	GMP status	DML renewal inspection conducted on 02.03.2021 and renewed the DML up to 2025
	Remarks of the Evaluator ³ .	Firm has eye drops (general) section as per renewal of DML letter
		dated 11-04-2016.
		Evidence of approval of applied formulation in reference regulatory
		authorities/agencies which were adopted by the Registration Board in
		its 275th meeting.
		royal of applied formulation in reference regulatory
0.5	Name and address of manufacturer /	d by the Registration Board in its 275th meeting.
85.		M/s Searle IV Solutions Pvt Ltd 1.5 km, Manga Raiwind Road, Lahore
	Applicant Brand Name +Dosage Form + Strength	
	Composition	Nevan Opthalmic Suspension Each ml Contains:
	Composition	Nepafenac1mg
	Diary No. Date of R& I & fee	Dy No. 14047: 07-03-2019
	Diary No. Date of Rec 1 & Ice	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-inflammatory agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
·		

Regulatory Authorities. Metoo Status Acukat Ophthalmic Suspension by Genix Pharma DMI. renewal inspection conducted on 02.03.2021 and renewed the DML up to 2025 Remarks of the Evaluator ³ . Firm shal submit 7.500/- fee for revision of specifications as per renewal of DML letter dated 11-04-2016. Decision: Approved with Innovator's specifications as per notification No.F.7-11/2012- BRADDRAP dated 07-08-2021. 86. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each Film Coated Tablet Contains: Lacosamide50mg Diary No. Date of R& L& fee Diary No. Date of R& I. & fee Diary No. Date of Form Finished Product Specification Fach Film Coated Tablet Contains: Lacosamide50mg Diary No. Date of R& I. & fee Dy No. 1521.37 (7-03-2019) PKR 20,0000: 06-03-2019 Pharmacological Group Other antiepleptics Type of Form Finished Product Specification BP Pack size & Demanded Price Approved. Metoo status GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019. Remarks of the Evaluator ² . Decision: Approved. Registration letter will be issued after submission of updated GMP inspection report by the firm. Mes Registration letter will be issued after submission of updated GMP inspection report by the firm. Mes Registration letter will be issued after submission of updated GMP inspection report by the firm. PRADONON: 06-03-2019 Pharmacological Group Diary No. Date of R& 1 & fee Dy No. 1521.67 (7-03-2019) PKR 20,000: 06-03-2019 PK	Regulatory Authorities. Me-too status Me-too status Me-too status Me-too status Me-too status Me-too status DML renewal inspection conducted on 02.03.2021 and renewed the DML up to 2025 Firm shal submit 7,500°- fee for revision of specifications as per renewal of DML letter dated 11.04-2016. Decision: Approved with Innovator's specifications Firm shal submit 7,500°- fee for revision of specifications as per notification No.F.7-11/2012- B&A/DRAP dated 07-08-2021. Mis Shaigan Pharmaceuticals (Pv) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi. Brand Name +Dosage Form + Strength Composition Diary No. Date of R&1 & fee Dy No. 15213 -70-32-019 Pharmacological Group Diary No. Date of R&1 & fee Dy No. 15213 -70-32-019 Pharmacological Group Other anticpileptics Type of Form Form 5 Finished Product Specification BP Pack size & Demanded Price Applicant GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019. Decision: Approved. Remarks of the Evaluator ² . Decision: Approved. Registration letter will be issued after submission of updated GMP inspection report by the firm. Mrs Shaigan Pharmaceuticals (Pv) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi. Brand Name +Dosage Form + Strength Composition Mrs Dajagan Harmaceuticals (Pv) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi. Brand Name +Dosage Form + Strength Composition Mrs Dajagan Harmaceuticals (Pv) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi. Remarks of the Evaluator ³ . Decision: Approved. Remarks of the Evaluator ⁴ . Decision: Approved. Remarks of the Evaluat			
Me-too status Acukat Ophthalmic Suspension by Genis Pharma	Me-too status		Approval status of product in Reference	MHRA Approved
GMP status DMI. renewal inspection conducted on 02.03.2021 and renewed the DML up to 2025 Firm has eye drops (general) section as per renewal of DMI. letter dated 11-04-2016. Decision: Approved with Innovator's specifications Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012- R&A/DRAP dated 07-05-2021. Brand Name +Dosage Form + Strength Composition Composit	GMP status DML, renewal inspection conducted on 02.03.2021 and renewed the DML up to 2025			
Remarks of the Evaluators. Remarks of the Fivaluators. Pirm shall submit 7,500- fee for revision of specifications as per renewal of DML letter dated 11-04/2016. Remarks of the Evaluators. Name and address of manufacturer / Mrs Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi. Brand Name +Dosage Form + Strength Composition LacosamideSubmy Diary No. Date of R& L& fee Dy No. 15213: 07-03-2019 Pharmacological Group Other anticplieptics Type of Form Forms Pirmisked Product Specification BP Pack size & Demanded Price Approved. Registration letter will be issued after submission of updated GMP inspection report by the firm. Remarks of the Evaluator. Diary No. Date of R& L& fee Dy No. 15213: 07-03-2019 Pharmacological Group Other anticplieptics Type of Form Form 5 Pirmisked Product Specification BP Pack size & Demanded Price Approved. Registration letter will be issued after submission of updated GMP inspection report by the firm. Remarks of the Evaluator. Decision: Approved. Remarks of the Evaluator. Diary No. Date of R& L& fee Oy No. 15213: 07-03-2019 PKR 20,0004: 06-03-2019. Remarks of the Forms Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi. Diary No. Date of R& L& fee Oy No. 15213: 07-03-2019 PKR 20,0004: 06-03-2019 P	Remarks of the Evaluator ³ . Remarks of the Evaluator ³ . Decision: Approved with Innovator's specifications. 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. RANDRAP dated 07-05-2021. RANDRAP dated 07-05-2021. Mass and address of manufacturer / M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi. Composition			
Remarks of the Evaluator ³ . Pirm shal submit 7,500/ fee for revision of specifications as per notification No.F.7-11/2012- BRA/DRAP dated 07-05-2012 Brand Name 4Dosage Form + Strength Composition Diary No. Date of R& 1 & fee Approval status of product in Reference Regulatory Authorities. Memand address of manufacturer / Applicant Diary No. Date of R& 1 & fee Approval status of product in Reference Regulatory Authorities. Memand address of manufacturer / Applicant Diary No. Date of R& 1 & fee Diary No. Date of R& 1 & fee Approval status of product in Reference Regulatory Authorities. Memand Name 4 Dosage Form + Strength Composition Diary No. Date of R& 1 & fee Diary No. 15212: 07-03-2019 PKR 20,000/-: 06-03-2019 PKR 20,0000/-: 06-03-2019 PKR 20,0000/-: 06-03-2019 PKR 20,0000/-: 06-03-2019 PKR 20,0000/-: 0	Remarks of the Evaluator ³ . Pirm has eye drops (general) section as per renewal of DMI. letter dated 11-04-2016. Decision: Approved with Innovator's specifications. Firm shall submit 7,500/ fee for revision of specifications as per notification No.F.7-11/2012-R&A/DRAP dated 07-05-2019. 86. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& 1& fee Diary No. Date of R& 1 & fee Diary No. Date of R& 1 & fee Approval status of product in Reference Regulatory Authorities. Me-too status CMP estrificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019. Pharmacological Group Tope of Form Remarks of the Evaluator ³ . Decision: Approved. **Name and address of manufacturer / M/S Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi. **Type of Form Form Form Series of the Evaluator Series of the Series of the Evaluator Series o		GMP status	•
Decision: Approved with Innovator's specifications.	dated 11-04-2016.			1
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Approval status of product in Reference Regulatory Authorities. Me-too status GMP status GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019. Remarks of the Evaluator ³ . Decision: Approved. Registration letter will be issued after submission of updated GMP inspection report by the firm. 88. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Brand Name +Dosage Form + Strength Composition Brand Name +Osage Form + Strength Ranidin Injection 50mg Brand Name +Osage Form + Strength Composition Brand Name +Osage Form + Strength Ranidin Injection 50mg Brand Name +Osage Form + Strength Composition Brand Name +Osage Form + Strength Ranidin Injection 50mg Brand Name +Osage Form + Strength Ranid	Approval status of product in Reference Regulatory Authorities. Me-too status GMP status GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019. Remarks of the Evaluator³. Decision: Approved. Registration letter will be issued after submission of updated GMP inspection report by the firm. 88. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Brand Name +Dosage Form + Strength Composition Each 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mg Diary No. Date of R& I & fee Dy No. 15198: 07-03-2019 Pharmacological Group H2 - receptor antagonist Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO		Finished Product Specification	BP
Regulatory Authorities. Me-too status GMP status GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019. Remarks of the Evaluator ³ . Decision: Approved. Registration letter will be issued after submission of updated GMP inspection report by the firm. 88. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Brand Name +Dosage Form + Strength Composition Each 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mg Diary No. Date of R& I & fee Dy No. 15198: 07-03-2019 Pharmacological Group Pharmacological Group Type of Form Form 5 Finished Product Specification Pack size & Demanded Price As per SRO MHRA Approved	Regulatory Authorities. Me-too status GMP status GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019. Remarks of the Evaluator ³ . Decision: Approved. Registration letter will be issued after submission of updated GMP inspection report by the firm. 88. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Brand Name +Dosage Form + Strength Composition Each 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mg Diary No. Date of R& I & fee Dy No. 15198: 07-03-2019 PKR 20,000/-: 06-03-2019 Pharmacological Group H2 - receptor antagonist Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO		Pack size & Demanded Price	As per SRO
Me-too status GMP status GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019. Remarks of the Evaluator³. Decision: Approved. Registration letter will be issued after submission of updated GMP inspection report by the firm. 88. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Brand Name +Dosage Form + Strength Composition Each 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mg Diary No. Date of R& I & fee Dy No. 15198: 07-03-2019 Pharmacological Group H2 - receptor antagonist Type of Form Form 5 Finished Product Specification Pack size & Demanded Price As per SRO Approval status of product in Reference MHRA Approved	Me-too status GMP status GMP certificate issued to the firm on 28-08-2020 based on inspection conducted on 25-09-2019. Remarks of the Evaluator³. Decision: Approved. • Registration letter will be issued after submission of updated GMP inspection report by the firm. 88. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mg Diary No. Date of R& I & fee Dy No. 15198: 07-03-2019 Pharmacological Group Pharmacological Group H2 - receptor antagonist Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO			MHRA Approved
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Inspection conducted on 25-09-2019. Remarks of the Evaluator ³ . Decision: Approved.	inspection conducted on 25-09-2019. Remarks of the Evaluator ³ . Decision: Approved. Registration letter will be issued after submission of updated GMP inspection report by the firm. 88. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mg Diary No. Date of R& I & fee Dy No. 15198: 07-03-2019 Pharmacological Group Pharmacological Group H2 - receptor antagonist Type of Form Form 5 Finished Product Specification Pack size & Demanded Price As per SRO			
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• Registration letter will be issued after submission of updated GMP inspection report by the firm. 88. Name and address of manufacturer / Applicant Office Daghal, Rawalpindi. Brand Name +Dosage Form + Strength Ranidin Injection 50mg Composition Each 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mg Diary No. Date of R& I & fee Dy No. 15198: 07-03-2019 Pharmacological Group H2 - receptor antagonist Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference MHRA Approved	• Registration letter will be issued after submission of updated GMP inspection report by the firm. 88. Name and address of manufacturer / Applicant		Remarks of the Evaluator ³ .	
88.Name and address of manufacturer / ApplicantM/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi.Brand Name +Dosage Form + StrengthRanidin Injection 50mgCompositionEach 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mgDiary No. Date of R& I & feeDy No. 15198: 07-03-2019 PKR 20,000/-: 06-03-2019Pharmacological GroupH2 - receptor antagonistType of FormForm 5Finished Product SpecificationUSPPack size & Demanded PriceAs per SROApproval status of product in ReferenceMHRA Approved	88.Name and address of manufacturer / ApplicantM/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi.Brand Name +Dosage Form + StrengthRanidin Injection 50mgCompositionEach 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mgDiary No. Date of R& I & feeDy No. 15198: 07-03-2019 PKR 20,000/-: 06-03-2019Pharmacological GroupH2 - receptor antagonistType of FormForm 5Finished Product SpecificationUSPPack size & Demanded PriceAs per SRO		Decision: Approved.	
88.Name and address of manufacturer / ApplicantM/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi.Brand Name +Dosage Form + StrengthRanidin Injection 50mgCompositionEach 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mgDiary No. Date of R& I & feeDy No. 15198: 07-03-2019 PKR 20,000/-: 06-03-2019Pharmacological GroupH2 - receptor antagonistType of FormForm 5Finished Product SpecificationUSPPack size & Demanded PriceAs per SROApproval status of product in ReferenceMHRA Approved	88.Name and address of manufacturer / ApplicantM/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi.Brand Name +Dosage Form + StrengthRanidin Injection 50mgCompositionEach 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mgDiary No. Date of R& I & feeDy No. 15198: 07-03-2019 PKR 20,000/-: 06-03-2019Pharmacological GroupH2 - receptor antagonistType of FormForm 5Finished Product SpecificationUSPPack size & Demanded PriceAs per SRO		Registration letter will be issue	ed after submission of updated GMP inspection report by the firm.
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Composition Each 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mg Diary No. Date of R& I & fee Dy No. 15198: 07-03-2019 PKR 20,000/-: 06-03-2019 Pharmacological Group H2 – receptor antagonist Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference MHRA Approved	Composition Each 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mg Diary No. Date of R& I & fee Dy No. 15198: 07-03-2019 PKR 20,000/-: 06-03-2019 Pharmacological Group H2 – receptor antagonist Type of Form Form 5 Finished Product Specification Pack size & Demanded Price Lach 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine50mg Dy No. 15198: 07-03-2019 FKR 20,000/-: 06-03-2019 H2 – receptor antagonist Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO			
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Pack size & Demanded Price As per SRO Approval status of product in Reference MHRA Approved	Pack size & Demanded Price As per SRO			
Approval status of product in Reference MHRA Approved				
				MHRA Approved
Regulatory Authorities.	Regulatory Authorities.		Regulatory Authorities.	

	Me-too status	Zantac injection by GSK
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on
	Givii status	
	D 1 C. 4 E 1 4 3	inspection conducted on 25-09-2019.
	Remarks of the Evaluator ³ .	
	containing medicinal products.	reference regulatory authorities regarding ranitidine
89.	Name and address of manufacturer /	M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post
89.	Applicant	Office Daghal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Topsar 20mg Tablet
	Composition	Each Tablet Contains:
	Composition	Telmisartan20mg
	Diary No. Date of R& I & fee	Dy No. 15201: 07-03-2019
	Diary No. Date of R& 1 & fee	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	MIRKA Approved
	Me-too status	Telsan Tablet by Hilton
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on
	GWF status	
	D 1 C1 E 1 3	inspection conducted on 25-09-2019.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
0.0		ed after submission of updated GMP inspection report by the firm.
90.	Name and address of manufacturer /	M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post
	Applicant	Office Daghal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Topsar 40mg Tablet
	Composition	Each Tablet Contains:
	D' N D (CD 0 I 0 C	Telmisartan40mg
	Diary No. Date of R& I & fee	Dy No. 15202: 07-03-2019
	Dhama alaini Carr	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities. Me-too status	Telsan Tablet by Hilton
	GMP status	, , , , , , , , , , , , , , , , , , ,
	GWP status	GMP certificate issued to the firm on 28-08-2020 based on
		inspection conducted on 25-09-2019.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
		ed after submission of updated GMP inspection report by the firm.
91.	Name and address of manufacturer /	M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post
	Applicant	Office Daghal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Topsar 80mg Tablet
	Composition	Each Tablet Contains:
	Di N D CDO VO C	Telmisartan80mg
	Diary No. Date of R& I & fee	Dy No. 15203: 07-03-2019
	DI 1 1 1 C	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Telsan Tablet by Hilton
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on
		inspection conducted on 25-09-2019.
i	Remarks of the Evaluator ³ .	

2.	Registration letter will be issue Name and address of manufacturer /	ed after submission of updated GMP inspection report by the firm. M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post
۷.	Applicant	Office Daghal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Velsar 80mg Tablet
	Composition	Each Film Coated Tablet Contains:
	Composition	Valsartan80mg
	Diary No. Date of R& I & fee	Dy No. 15204: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Valtec Tablets by Tabros
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on
		inspection conducted on 25-09-2019.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
		ed after submission of updated GMP inspection report by the firm.
3.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Pos Office Daghal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Velsar 160mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Valsartan160mg
	Diary No. Date of R& I & fee	Dy No. 15205: 07-03-2019
	DI 1 ' 1 C	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price Approval status of product in Reference	As per SRO MHRA Approved
	Regulatory Authorities.	WITKA Approved
	Me-too status	Valtec Tablets by Tabros
	GMP status	GMP certificate issued to the firm on 28-08-2020 based on
	STAT SWANGS	inspection conducted on 25-09-2019.
	Remarks of the Evaluator ³ .	inspection conducted on 25 07 2017.
	Decision: Approved.	<u>l</u>
		ed after submission of updated GMP inspection report by the firm.
١.	Name and address of manufacturer /	M/s Shrooq Pharmaceuticals Pvt Ltd 21-km Ferozpur Road,
	Applicant	Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Sarpin Tablet 5/80mg
	Composition	Each Film Coated Tablet Contains:
		Amlodipine as Besylate5mg
		Valsartan80mg
	Diary No. Date of R& I & fee	Dy No. 14951: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Exforge Tablet by Novartis
	GMP status	GMP certificate issued to M/s Shrooq Pharma based upon
		evaluation conducted on 29-10-2021.
	Remarks of the Evaluator ³	
	Remarks of the Evaluator ³ . Decision: Approved.	<u> </u>
5.	Remarks of the Evaluator ³ . Decision: Approved. Name and address of manufacturer /	M/s Shrooq Pharmaceuticals Pvt Ltd 21-km Ferozpur Road,

	Brand Name +Dosage Form + Strength	Sarpin Tablet 10/320mg
	Composition	Each Film Coated Tablet Contains:
	Composition	Amlodipine as Besylate10mg
		Valsartan320mg
	Diary No. Date of R& I & fee	Dy No. 14951: 07-03-2019
	Biary 110. Bate of fee fee	PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Exforge Tablet by Novartis
	GMP status	GMP certificate issued to M/s Shrooq Pharma based upon
		evaluation conducted on 29-10-2021.
	Remarks of the Evaluator ³ .	evaluation conducted on 2) 10 2021.
	Decision: Approved.	
96.	Name and address of manufacturer /	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road,
70.	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Amoval 5/80mg Tablet
	Composition	Each Tablet Contains:
	1	Amlodipine as Besylate5mg
		Valsartan80mg
	Diary No. Date of R& I & fee	Dy No. 13438: 07-03-2019
		PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Exforge Tablet by Novartis
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel
		recommended the renewal of DML.
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
		innovator's product as per following:
		Each Film Coated Tablet Contains:
		Amlodipine as Besylate5mg
		Valsartan80mg
	Decision: Approved with following laber Each Film Coated Tablet Con	
	Amlodipine as Besylate5mg	
	Valsartan80mg	
		d after submission of updated GMP inspection report by the firm.
		or revision of formulation from film uncoated tablet to film coated
		7-11/2012-B&A/DRAP dated 07-05-2021.
97.	Name and address of manufacturer /	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Amoval 5/160mg Tablet
	Composition	Each Tablet Contains:
		Amlodipine as Besylate5mg
		Valsartan160mg
	Diary No. Date of R& I & fee	Dy No. 13439: 07-03-2019
		PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
1	Regulatory Authorities.	
	Me-too status	Exforge Tablet by Novartis

GMP status	Panel inspection conducted on 18-02-2020 wherein the panel
	recommended the renewal of DML.
Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
	innovator's product as per following:
	Each Film Coated Tablet Contains:
	Amlodipine as Besylate5mg
	Valsartan160mg

Each Film Coated Tablet Contains:

Amlodipine as Besylate...5mg

Valsartan...160mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of formulation from film uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

98.	Name and address of manufacturer /	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Amoval 10/160mg Tablet
	Composition	Each Tablet Contains:
		Amlodipine as Besylate10mg
		Valsartan160mg
	Diary No. Date of R& I & fee	Dy No. 13440: 07-03-2019
		PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Exforge Tablet by Novartis
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel
		recommended the renewal of DML.
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
		innovator's product as per following:
		Each Film Coated Tablet Contains:
		Amlodipine as Besylate10mg
		Valsartan160mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:

Amlodipine as Besylate...10mg

Valsartan...160mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- Firm shall submit 7,500/- fee for revision of formulation from film uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

99.	Name and address of manufacturer /	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Hepcon Infusion
	Composition	Each Vial Contains:
		L-OR&Ithine L-Aspartate5g/10ml
	Diary No. Date of R& I & fee	Dy No. 13436: 07-03-2019
		PKR 20,000/-: 05-03-2019
	Pharmacological Group	Amino Acid (Hepato Protective Lipotropic)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Hepa-Merz 5 g / 10 ml infusion solution concentrate (Austria
	Regulatory Authorities.	Approved) as 10ml ampoule
	Me-too status	Hepanil Infusion Concentrate 5gm/10ml by Medicraft
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel
		recommended the renewal of DML.
	Remarks of the Evaluator ³ .	• Evidence of required manufacturing facility / section approval letter
		from Licensing Division.

• The RRA approved product is available in 10ml ampoule while you
have applied the formulation in 10ml vial, clarification is required in
this regard.

Decision: Deferred for following submissions:

- Evidence of required manufacturing facility / section approval letter from Licensing Division.
- Clarification, since the reference product is available in 10ml ampoule while you have applied the formulation in 10ml vial.
- Evidence of requisite testing facility.

• Latest GMP inspection report conducted within a period of last three years.

100.	Name and address of manufacturer /	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Hepcon Syrup
	Composition	L-OR&Ithine L-Aspartate300mg/ml
		Nicotinamide24mg/5ml
		Riboflavin Sodium Phaspate0.76mg/5ml
	Diary No. Date of R& I & fee	Dy No. 13435: 07-03-2019
		PKR 20,000/-: 05-03-2019
	Pharmacological Group	Amino Acid (Hepato Protective Lipotropic)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Could not be confirmed
	Regulatory Authorities.	
	Me-too status	OR&Ivit Syrup by English Pharma
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel
		recommended the renewal of DML.
	Remarks of the Evaluator ³ .	Evidence of required manufacturing facility / section approval letter
		from Licensing Division.
		Evidence of approval of applied formulation in reference regulatory
		authorities/agencies which were adopted by the Registration Board in
		its 275th meeting.
		• Submit complete label claim as per RRA approved product along with submission of full fee.

Decision: Deferred for following submissions:

- Evidence of required manufacturing facility / section approval letter from Licensing Division.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
- Submission of complete label claim as per the innovator's product along with submission of full fee of registration.
- Evidence of requisite testing facility.

Latest GMP inspection report conducted within a period of last three years.

101.	Name and address of manufacturer /	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Rabrin 400mg Capsule
	Composition	Each Capsule Contains:
		Ribavirin400mg
	Diary No. Date of R& I & fee	Dy No. 13444: 07-03-2019
		PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Could not be confirmed
	Regulatory Authorities.	
	Me-too status	Xolox Capsule byFerozesons
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel
		recommended the renewal of DML.
	Remarks of the Evaluator ³ .	Evidence of approval of applied formulation in reference regulatory
		authorities/agencies which were adopted by the Registration Board in
		its 275th meeting.
	Decision: Deferred for following submi	ssions:

	were adopted by the Registrat	d formulation in reference regulatory authorities/agencies which ion Board in its 275th meeting. conducted within a period of last three years.
02.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Rabrin 400mg Tablet
	Composition	Each Tablet Contains:
		Ribavirin400mg
	Diary No. Date of R& I & fee	Dy No. 13441: 07-03-2019
		PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Alcorib tablets by Searle
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel
		recommended the renewal of DML.
	Remarks of the Evaluator ³ .	•
	Decision: Approved.	
		ed after submission of updated GMP inspection report by the firm.
03.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Rabrin 500mg Tablet
	Composition	Each Tablet Contains:
		Ribavirin500mg
	Diary No. Date of R& I & fee	Dy No. 13442: 07-03-2019
		PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Alcorib tablets by Searle
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel
		recommended the renewal of DML.
	Remarks of the Evaluator ³ .	•
	Decision: Approved.	
	Registration letter will be issued after submission of updated GMP inspection report by the firm.	
04.	Name and address of manufacturer /	M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road,
	Applicant	Lahore
	Brand Name +Dosage Form + Strength	Rabrin 600mg Tablet
	Composition	Each Tablet Contains:
	DI 37 D 37 C 7	Ribavirin400mg
	Diary No. Date of R& I & fee	Dy No. 13443: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Alcorib tablets by Searle
	CMD	Panel inspection conducted on 18-02-2020 wherein the panel
	GMP status	
	GMP status	recommended the renewal of DML.
	Remarks of the Evaluator ³ .	<u> </u>

105	NT	M/c C
105.	Name and address of manufacturer /	M/s Swiss Pharmaceuticals Pvt Ltd.
	Applicant	A-159, S.I.T.E Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Swicef 200mg Tablet
	Composition	Each Film Coated Tablet Contains:
	D'an Ma Data (DO LO Car	Cefixime as trihydrate200mg
	Diary No. Date of R& I & fee	Dy No. 16843: 07-03-2019
	Diamental Comme	PKR 20,000/-: 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	T' 1 T T T T T T T T T T T T T T T T T T
	Me-too status	Liskoxime Tablet by Lisko pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 18-
		03-2022.
	Remarks of the Evaluator ³ .	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Registration Board decided to	o reject the application since the firm does not have requisite
	manufacturing facility / section approv	
106.	Name and address of manufacturer /	M/s Swiss Pharmaceuticals Pvt Ltd.
	Applicant	A-159, S.I.T.E Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Celebox 100mg Capsule
	Composition	Each Capsule Contains:
	r	Celecoxib100mg
	Diary No. Date of R& I & fee	Dy No. 16850: 07-03-2019
	,	PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Cewim Capsule by Wimits pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 18-
		03-2022.
	Remarks of the Evaluator ³ .	• The applied product falls under WHO ATC class L01XX33 as well as M01AH01 and Registration Board in its 297 th meeting decided to allow the manufacturing of such type of drugs which fall in both "Antineoplastic (L01)" & "Immunosuppressants (L04)" class including everolimus and methotrextare etc. in the "Anti-cancer" section only (being high risk products).
	Decision: Approved.	section only (being mgn risk products).
107.	Name and address of manufacturer /	M/s Swiss Pharmaceuticals Pvt Ltd.
	Applicant	A-159, S.I.T.E Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Celebox 200mg Capsule
	Composition	Each Capsule Contains:
	1	Celecoxib200mg
	Diary No. Date of R& I & fee	Dy No. 16851: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	WITKA Approved
	Me-too status	Cewim Capsule by Wimits pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 18-
		03-2022.
	Remarks of the Evaluator ³ .	• The applied product falls under WHO ATC class L01XX33 as well as
	Remarks of the Evaluator .	M01AH01 and Registration Board in its 297 th meeting decided to

allow the manufacturing of such type of drugs which fall in both "Antineoplastic (L01)" & "Immunosuppressants (L04)" class including everolimus and methotrextare etc. in the "Anti-cancer" section only (being high risk products). Decision: Approved. 108. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Diary No. Tosat4: 07-03-2019 Pharmacological Group Anti-cmetic Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status GMP certificate issued on basis of inspection conducted on 18-03-2022. Remarks of the Evaluator ³ . * Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Diary No. Date of R& I & fee Dy No. 16852: 07-03-2019 PKR 20,000/-: 07-03-2019 PKR 20,000/-: 0			
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including everolimus and methotrextare etc. in the "Anti-cancer" section only (being high risk products). Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Doilum C 20/15 mg Tablet Composition Each Tablet Contains: Cinnarizine20mg Domperidone Maleate Eq. To Domperidone15mg Diary No. Date of R& I & fee Dy No. 16844: 07-03-2019 PKR 20,000/-: 07-03-2019 Pharmacological Group Anti-emetic Type of Form Finished Product Specification Firm has claimed in house specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status GMP certificate issued on basis of inspection conducted on 18- 03-2022. Remarks of the Evaluator³. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Mys Swiss Pharmaceuticals Pvt Ltd. A-159, S.1.T.E Super Highway, Karachi Fena 60mg Tablet Composition Face form Fena 60mg Tablet Composition Fena 60mg Tablet Fena 60mg Table			
Section only (being high risk products).			
Decision: Approved. Name and address of manufacturer / Applicant			
Name and address of manufacturer / Applicant A-159, S.I.T.E. Super Highway, Karachi			section only (being high risk products).
Applicant Brand Name +Dosage Form + Strength Dolium C 20/15 mg Tablet			
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Composition Each Tablet Contains: Cimarizine (2000)			
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Approval status of product in Reference Regulatory Authorities. Me-too status Dozin Tablet by Hilton Pharma GMP status GMP status GMP certificate issued on basis of inspection conducted on 18- 03-2022. Remarks of the Evaluator³. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each Film Coated Tablet Contains: Fexofenadine HCl60mg Diary No. Date of R& I & fee Dy No. 16852: 07-03-2019 Pharmacological Group Antihistamines For Systemic Use Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz			
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Regulatory Authorities. Me-too status GMP status GMP certificate issued on basis of inspection conducted on 18-03-2022. Remarks of the Evaluator ³ . • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. 109. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each Film Coated Tablet Contains: Fexofenadine HCL60mg Diary No. Date of R& I & fee Dy No. 16852: 07-03-2019 PKR 20,000/-: 07-03-2019 PKR 20,000/-: 07-03-2019 PKR 20,000/-: 07-03-2019 Pharmacological Group Antihistamines For Systemic Use Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz		Approval status of product in Reference	Could not be confirmed
Me-too status			
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Remarks of the Evaluator ³ . Remarks of the Evaluator ³ . Pevidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each Film Coated Tablet Contains: Fexofenadine HCl60mg Diary No. Date of R& I & fee Dy No. 16852: 07-03-2019 Pharmacological Group Antihistamines For Systemic Use Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz			
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authorities/agencies which were adopted by the Registration Board in its 275th meeting. Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. 109. Name and address of manufacturer / Applicant		Remarks of the Evaluator ³	Evidence of approval of applied formulation in reference regulatory
its 275th meeting. Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. 109. Name and address of manufacturer / Applicant A-159, S.I.T.E Super Highway, Karachi Brand Name +Dosage Form + Strength Fena 60mg Tablet Composition Each Film Coated Tablet Contains: Fexofenadine HC160mg Diary No. Date of R& I & fee Dy No. 16852: 07-03-2019 Pharmacological Group Antihistamines For Systemic Use Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz		remarks of the Evaluator.	
Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. 109. Name and address of manufacturer / Applicant			
authorities/agencies which were adopted by the Registration Board in its 275th meeting. 109. Name and address of manufacturer / Applicant			
109. Name and address of manufacturer / Applicant			
A-159, S.I.T.E Super Highway, Karachi Brand Name +Dosage Form + Strength Fena 60mg Tablet Composition Each Film Coated Tablet Contains: Fexofenadine HC160mg Diary No. Date of R& I & fee Dy No. 16852: 07-03-2019 PKR 20,000/-: 07-03-2019 Pharmacological Group Antihistamines For Systemic Use Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz		authorities/agencies which were adopte	ed by the Registration Board in its 275th meeting.
Brand Name +Dosage Form + Strength Fena 60mg Tablet Composition Each Film Coated Tablet Contains: Fexofenadine HC160mg Diary No. Date of R& I & fee Dy No. 16852: 07-03-2019 PKR 20,000/-: 07-03-2019 Pharmacological Group Antihistamines For Systemic Use Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz	109.	Name and address of manufacturer /	M/s Swiss Pharmaceuticals Pvt Ltd.
Brand Name +Dosage Form + Strength Fena 60mg Tablet Composition Each Film Coated Tablet Contains: Fexofenadine HC160mg Diary No. Date of R& I & fee Dy No. 16852: 07-03-2019 PKR 20,000/-: 07-03-2019 Pharmacological Group Antihistamines For Systemic Use Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz		Applicant	A-159, S.I.T.E Super Highway, Karachi
Composition Each Film Coated Tablet Contains: Fexofenadine HCl60mg Diary No. Date of R& I & fee Dy No. 16852: 07-03-2019 PKR 20,000/-: 07-03-2019 Pharmacological Group Antihistamines For Systemic Use Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz			
Fexofenadine HC160mg Diary No. Date of R& I & fee Dy No. 16852: 07-03-2019 PKR 20,000/-: 07-03-2019 Pharmacological Group Antihistamines For Systemic Use Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz			
Diary No. Date of R& I & fee Dy No. 16852: 07-03-2019 PKR 20,000/-: 07-03-2019 Pharmacological Group Antihistamines For Systemic Use Type of Form Form 5 Finished Product Specification Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Dy No. 16852: 07-03-2019 PKR 20,000/-: 07-03-2019 Event Systemic Use USP As per SRO USFDA Approved Fexet Tablets by Getz		Composition	
PKR 20,000/-: 07-03-2019 Pharmacological Group Antihistamines For Systemic Use Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz			
Pharmacological Group Antihistamines For Systemic Use Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz		Diary No. Date of R& I & fee	Dy No. 16852: 07-03-2019
Pharmacological Group Antihistamines For Systemic Use Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz			PKR 20,000/-: 07-03-2019
Type of Form Form 5 Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz		Pharmacological Group	
Finished Product Specification USP Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz		•	,
Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz			
Approval status of product in Reference Regulatory Authorities. Me-too status Fexet Tablets by Getz		•	
Regulatory Authorities. Me-too status Fexet Tablets by Getz		Pack size & Demanded Price	As per SRO
Regulatory Authorities. Me-too status Fexet Tablets by Getz		Approval status of product in Reference	USFDA Approved
Me-too status Fexet Tablets by Getz		1 11	11
,			Fovet Tableta by Cotz
GMP status GMP certificate issued on basis of inspection conducted on 18-			
		GMP status	GMP certificate issued on basis of inspection conducted on 18-
03-2022.			03-2022.
Remarks of the Evaluator ³ .		Remarks of the Evaluator ³	•
Decision: Approved.			
	110		MI-C-2-Di
110. Name and address of manufacturer / M/s Swiss Pharmaceuticals Pvt Ltd.	110.		
Applicant A-159, S.I.T.E Super Highway, Karachi		**	
Brand Name +Dosage Form + Strength Fena 120mg Tablet		Brand Name +Dosage Form + Strength	Fena 120mg Tablet
Composition Each Film Coated Tablet Contains:		Composition	Each Film Coated Tablet Contains:
Fexofenadine HC1120mg		1	
Diary No. Date of R& I & fee Dy No. 16853: 07-03-2019		Diam No Data of De I e for	
			1 1 2 V 1 N 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
		Diary No. Date of R& 1 & fee	
Pharmacological Group Antihistamines For Systemic Use			PKR 20,000/-: 07-03-2019
Type of Form Form 5		Pharmacological Group	
		Pharmacological Group	PKR 20,000/-: 07-03-2019 Antihistamines For Systemic Use
		Pharmacological Group Type of Form	PKR 20,000/-: 07-03-2019 Antihistamines For Systemic Use Form 5
		Pharmacological Group Type of Form Finished Product Specification	PKR 20,000/-: 07-03-2019 Antihistamines For Systemic Use Form 5 USP
		Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	PKR 20,000/-: 07-03-2019 Antihistamines For Systemic Use Form 5 USP As per SRO
Regulatory Authorities.		Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	PKR 20,000/-: 07-03-2019 Antihistamines For Systemic Use Form 5 USP
		Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	PKR 20,000/-: 07-03-2019 Antihistamines For Systemic Use Form 5 USP As per SRO
y .		Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	PKR 20,000/-: 07-03-2019 Antihistamines For Systemic Use Form 5 USP As per SRO USFDA Approved
1 Olym Common of Dispersion of the Common of		Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	PKR 20,000/-: 07-03-2019 Antihistamines For Systemic Use Form 5 USP As per SRO USFDA Approved Fexet Tablets by Getz
03-2022.		Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	PKR 20,000/-: 07-03-2019 Antihistamines For Systemic Use Form 5 USP As per SRO USFDA Approved Fexet Tablets by Getz GMP certificate issued on basis of inspection conducted on 18-

1	Remarks of the Evaluator ³ .	•
	Decision: Approved.	
111.	Name and address of manufacturer /	M/s Swiss Pharmaceuticals Pvt Ltd.
	Applicant	A-159, S.I.T.E Super Highway, Karachi
	Brand Name +Dosage Form + Strength	K-Cit Tablet
	Composition	Each Extended Release Tablet Contains:
		Potassium Citrate10mg
	Diary No. Date of R& I & fee	Dy No. 16845: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Mineral Supplements
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	Little in Table 1. Con
	Me-too status	Lithocit Tablet by Getz
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator ³ .	Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each Extended Release Tablet Contains:
		Potassium Citrate10mEq (1080mg)
	Decision: Approved with following lab	
	Each Extended Release T	
	Potassium Citrate10n	1 ()
		s. 30,000/- for correction/pre-approval change in product label claim
	as per nouncation No.F./-11/2 letter.	012-B&A/DRAP dated 07-05-2021, before issuance of registration
112.	Name and address of manufacturer /	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B
	Applicant	Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Xofyl 200mg Tablet
1		
	Composition	Each Tablet Contains:
	-	Doxofylline200mg
	Composition Diary No. Date of R& I & fee	Doxofylline200mg Dy No. 16053: 07-03-2019
	Diary No. Date of R& I & fee	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019
	Diary No. Date of R& I & fee Pharmacological Group	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases
	Diary No. Date of R& I & fee Pharmacological Group Type of Form	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5
	Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications
	Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO
	Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed
	Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed Could not be confirmed
	Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed
	Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed Could not be confirmed GMP certificate issued based upon inspection conducted on 28-02-2020 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Diary No. Date of R& I & 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 ³ .	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed Could not be confirmed GMP certificate issued based upon inspection conducted on 28-02-2020 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in
	Diary No. Date of R& I & 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 ³ .	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed Could not be confirmed GMP certificate issued based upon inspection conducted on 28-02-2020 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Diary No. Date of R& I & 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 ³ . Decision: Deferred for following: • Evidence of applied formulation/d	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed Could not be confirmed GMP certificate issued based upon inspection conducted on 28-02-2020 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Diary No. Date of R& I & 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 ³ . Decision: Deferred for following: • Evidence of applied formulation/d registration number, brand name a	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed Could not be confirmed GMP certificate issued based upon inspection conducted on 28-02-2020 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Diary No. Date of R& I & 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 ³ . Decision: Deferred for following: • Evidence of applied formulation/d registration number, brand name as • Evidence of approval of applied formulation/d	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed Could not be confirmed GMP certificate issued based upon inspection conducted on 28-02-2020 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Formulation in reference regulatory authorities/agencies which were
112	Diary No. Date of R& I & 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 ³ . Decision: Deferred for following: • Evidence of applied formulation/d registration number, brand name a endopted by the Registration Board	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed Could not be confirmed GMP certificate issued based upon inspection conducted on 28-02-2020 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Formulation in reference regulatory authorities/agencies which were in its 275th meeting.
113.	Diary No. Date of R& I & 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 ³ . Decision: Deferred for following: • Evidence of applied formulation/d registration number, brand name a dopted by the Registration Board Name and address of manufacturer /	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed Could not be confirmed GMP certificate issued based upon inspection conducted on 28-02-2020 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Formulation in reference regulatory authorities/agencies which were in its 275th meeting. M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B
113.	Diary No. Date of R& I & 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 ³ . Decision: Deferred for following: • Evidence of applied formulation/d registration number, brand name a dopted by the Registration Board Name and address of manufacturer / Applicant	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed Could not be confirmed GMP certificate issued based upon inspection conducted on 28-02-2020 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Formulation in reference regulatory authorities/agencies which were in its 275th meeting. M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi
113.	Diary No. Date of R& I & 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 ³ . Decision: Deferred for following: • Evidence of applied formulation/d registration number, brand name a dopted by the Registration Board Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed Could not be confirmed GMP certificate issued based upon inspection conducted on 28-02-2020 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Formulation in reference regulatory authorities/agencies which were in its 275th meeting. M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi Xofyl Injection 100mg/10ml
113.	Diary No. Date of R& I & 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 ³ . Decision: Deferred for following: • Evidence of applied formulation/d registration number, brand name a dopted by the Registration Board Name and address of manufacturer / Applicant	Doxofylline200mg Dy No. 16053: 07-03-2019 PKR 20,000/-: 06-03-2019 Other Systemic Drugs For Obstructive Airway Diseases Form 5 Firm has claimed in-house specifications As per SRO Could not be confirmed Could not be confirmed GMP certificate issued based upon inspection conducted on 28-02-2020 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Formulation in reference regulatory authorities/agencies which were in its 275th meeting. M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi

·	PKR 20,000/-: 06-03-2019
Pharmacological Group	NSAID
Type of Form	Form 5
Finished Product Specification	BP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
Me-too status	Could not be confirmed
GMP status	GMP certificate issued based upon inspection conducted on 28-02-2020
Remarks of the Evaluator ³ .	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

114.	Name and address of manufacturer /	M/s Trillium Pharmaceuticals Pvt Ltd. Plot No. C-3 & C-4, Value
	Applicant	Addition City, Faisalabad
	Brand Name +Dosage Form + Strength	Tridic SR 50mg Capsule
	Composition	Each Capsule Contains SR Pellets:
		Diclofenac Sodium SR Pellets50mg
	Diary No. Date of R& I & fee	Dy No. 16427: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Could not be confirmed
	Regulatory Authorities.	
	Me-too status	Ayanac 50mg SR Capsule
	GMP status	
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
		• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).
		• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

Decision: Deferred for following:

- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
- Source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).

Latest GMP inspection report conducted within a period of last three years.

115.	Name and address of manufacturer /	M/s Trillium Pharmaceuticals Pvt Ltd. Plot No. C-3 & C-4, Value
	Applicant	Addition City, Faisalabad
	Brand Name +Dosage Form + Strength	Tridic SR 100mg Capsule
	Composition	Each Capsule Contains SR Pellets:
		Diclofenac Sodium SR Pellets100mg
	Diary No. Date of R& I & fee	Dy No. 16428: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO

Approval status of product in Reference	MHRA Approved
Regulatory Authorities.	
Me-too status	Arthonil Capsule by Batala Pharma
GMP status	
Remarks of the Evaluator ³ .	 Latest GMP inspection report conducted within a period of last three years. Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Diclofenac sodium (as SR pellets)100mg

Each Capsule Contains:

Diclofenac sodium (as SR pellets)...100mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter
- Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.

116.	Name and address of manufacturer /	M/s Trison Research Laboratories Pvt Ltd. 27-A, Punjab Small
	Applicant	Industries Estate, Sargodha
-	Brand Name +Dosage Form + Strength	Detrin 8mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Ondansetron8mg
	Diary No. Date of R& I & fee	Dy No. 13633: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Danset Tablet by CCL
	GMP status	
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
		• Revise your label claim along with submission of full fee as per the innovator's product as per following:
		Each Film Coated Tablet Contains:
		Ondansetron (as hydrochloride dihydrate)8mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:

Ondansetron (as hydrochloride dihydrate)...8mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

117.	Name and address of manufacturer /	M/s Trison Research Laboratories Pvt Ltd. 27-A, Punjab Small
	Applicant	Industries Estate, Sargodha
	Brand Name +Dosage Form + Strength	Triglip 50/500 mg Tablet
	Composition	Each Film Tablet Contains:
		Sitagliptin as Sitagliptin Phosphate Monohydrate50mg
		Metformin HCl500mg
	Diary No. Date of R& I & fee	Dy No. 13643: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Treivamet Tablet by Getz
	GMP status	
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's s	
		ed after submission of updated GMP inspection report by the firm.
		or revision of specifications as per notification No.F.7-11/2012-
118.	Name and address of manufacturer /	M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad
110.	Applicant	Industrial Estate, Peshawar
	Brand Name +Dosage Form + Strength	Hepdisol 200mg Tablet
		Each Tablet Contains:
	Composition	
		Rifaximin200mg
	Diary No. Date of R& I & fee	Dy No. 16437: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
		A '1-1 T-11 (1 C (' D)
	Me-too status	Axibol Tablet by Genetics Pharma
	GMP status	Date of Inspection 31-12-2021. Satisfactory level of GMP compliance.
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
		innovator's product as per following:
		Each Film Coated Tablet Contains:
		Rifaximin200mg
		el claim:
		tains: or revision of formulation from uncoated tablet to film coated tablet
119.	Rifaximin200mg • Firm shall submit 7,500/- fee for as per notification No.F.7-11/2	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021.
119.	Rifaximin200mg • Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer /	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad
119.	Rifaximin200mg • Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant	or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar
119.	Rifaximin200mg • Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet
119.	Rifaximin200mg • Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains:
119.	Rifaximin200mg • Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg
119.	Rifaximin200mg • Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019
119.	Rifaximin200mg • Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019
119.	Rifaximin200mg • Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics
119.	Rifaximin200mg • Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP
119.	Rifaximin200mg • Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma Date of Inspection 31-12-2021. Satisfactory level of GMP compliance.
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma Date of Inspection 31-12-2021. Satisfactory level of GMP compliance. • Revise your label claim along with submission of 7500 fee as per the
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma Date of Inspection 31-12-2021. Satisfactory level of GMP compliance. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following:
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma Date of Inspection 31-12-2021. Satisfactory level of GMP compliance. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains:
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma Date of Inspection 31-12-2021. Satisfactory level of GMP compliance. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin550mg
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labely as per notification in the status i	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma Date of Inspection 31-12-2021. Satisfactory level of GMP compliance. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin550mg
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laborator and product and product contains the contains and product and product contains are product and product and product and product contains are product and product contains and product contains are product and product contains and product contains and product contains are product and product contains and product contains are product and product contains are product contains and product contains are product contains and product contains and product contains are product contains and product contains and product contains are product contains and product contains and product contains are product contains and product contains and product contains are product contains and product contains and product contains are product contains and product contains and product contains are product contains and product contains and product contains are product contains and product contains and product contains are product contains and product contains and product contains are product contains and product contains are product contains and product contains and product contains and product contains are product contains and product contains and product contains are product contains and product contains and product contains are product contains and product contains and product contains are product contains and product contains are product contains and product contains and product contains are product contains and product contains and product contains and product contains and product contains are product contains and product contains and product contains are product contains and	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma Date of Inspection 31-12-2021. Satisfactory level of GMP compliance. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin550mg
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labor Each Film Coated Tablet Contaction Rifaximin550mg	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma Date of Inspection 31-12-2021. Satisfactory level of GMP compliance. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin550mg el claim: tains:
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labe Each Film Coated Tablet Contagination550mg Firm shall submit 7,500/- fee for	revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma Date of Inspection 31-12-2021. Satisfactory level of GMP compliance. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin550mg el claim: tains:
	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labe Each Film Coated Tablet Contents Rifaximin550mg Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma Date of Inspection 31-12-2021. Satisfactory level of GMP compliance. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin550mg el claim: tains: revision of formulation from uncoated tablet to film coated tablet as B&A/DRAP dated 07-05-2021.
119.	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laber Each Film Coated Tablet Contents Rifaximin550mg Firm shall submit 7,500/- fee for per notification No.F.7-11/2012- Name and address of manufacturer /	revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma Date of Inspection 31-12-2021. Satisfactory level of GMP compliance. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin550mg el claim: tains:
	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labor Each Film Coated Tablet Contact Rifaximin550mg Firm shall submit 7,500/- fee for per notification No.F.7-11/2012- Name and address of manufacturer / Applicant	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma Date of Inspection 31-12-2021. Satisfactory level of GMP compliance. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin550mg el claim: tains: revision of formulation from uncoated tablet to film coated tablet as B&A/DRAP dated 07-05-2021.
	Rifaximin200mg Firm shall submit 7,500/- fee for as per notification No.F.7-11/2 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laber Each Film Coated Tablet Contents Rifaximin550mg Firm shall submit 7,500/- fee for per notification No.F.7-11/2012- Name and address of manufacturer /	tains: or revision of formulation from uncoated tablet to film coated tablet 012-B&A/DRAP dated 07-05-2021. M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar Hepdisol 550mg Tablet Each Tablet Contains: Rifaximin550mg Dy No. 16438: 07-03-2019 PKR 20,000/-: 07-03-2019 Antibiotics Form 5 BP As per SRO MHRA Approved Axibol Tablet by Genetics Pharma Date of Inspection 31-12-2021. Satisfactory level of GMP compliance. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin550mg el claim: tains: revision of formulation from uncoated tablet to film coated tablet as B&A/DRAP dated 07-05-2021.

	Composition	Each Tablet Contains:
	Di N D GDO YO G	Amisulpride100mg
	Diary No. Date of R& I & fee	Dy No. 14418: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Amis Tablets by Genome Pharmaceuticals
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP
		was reported
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved.	
101		ued after submission of updated GMP inspection report by the firm.
121.	Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
	Brand Name +Dosage Form + Strength	U Metab 50mg Tablet
	Composition	Each Tablet Contains:
	Composition	Clomifene Citrate50mg
	Diary No. Date of R& I & fee	Dy No. 14424: 07-03-2019
	Diary No. Date of R& 1 & fee	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Ovulation stimulants, synthetic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Vogi Tablet by Genix Pharma
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Roard approved	registration of product in general manufacturing areas with
		ide safety and protective measures for workers and personnel which
	remain in direct contact or are involved	
		ued after submission of updated GMP inspection report by the firm.
122.	Name and address of manufacturer /	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
122.	Applicant	Wis Osawa Filarmaceuticais 140 S.1.Z. Risaipur, KFK, Fakistan
	Brand Name +Dosage Form + Strength	Awaxetine 20mg Capsule
	Composition	Each Delayed Release Capsule Contains:
	Composition	Duloxetine As Hcl20mg
	Diary No. Date of R& I & fee	Dy No. 14428: 07-03-2019
	Dimy 110. Dute of No. 1 of Ice	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antidepressant
		Form 5
	Type of Form	
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dulan Capsule by Hilton
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator ³ .	 Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). Revise your label claim along with submission of full fee as per the innovator's product as per following:
		Each Capsule Contains: Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine20mg
		Durozonie iroi Enteric Coateu i enets Eq. 10 Durozonie2011g

Each Capsule Contains:

Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine...20mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter
- Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.

M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
Awaxetine 30mg Capsule
Each Delayed Release Capsule Contains:
Duloxetine As Hcl30mg
Dy No. 14429: 07-03-2019
PKR 20,000/-: 06-03-2019
Other antidepressant
Form 5
USP
As per SRO
MHRA Approved
Dulan Capsule by Hilton
Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).
 Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine30mg

Decision: Approved with following label claim:

Each Capsule Contains:

Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine...30mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.
- Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.

124.	Name and address of manufacturer /	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
	Applicant	
	Brand Name +Dosage Form + Strength	Awaxetine 60mg Capsule
	Composition	Each Delayed Release Capsule Contains:
		Duloxetine As Hcl60mg
	Diary No. Date of R& I & fee	Dy No. 14435: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Dulan Capsule by Hilton
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP
		was reported
	Remarks of the Evaluator ³ .	• Provide source of pellets along with COA, stability study data of 3
		batches of pellets, GMP certificate of pellets manufacturer and
		differential fee (in case of imported pellets).

	• Revise your label claim along with submission of full fee as per the
	innovator's product as per following:
	Each Capsule Contains:
	Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine60mg

Each Capsule Contains:

Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine...60mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.
- Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.

125.	Name and address of manufacturer /	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
	Applicant	
	Brand Name +Dosage Form + Strength	Floxet Capsule 20mg
	Composition	Each Capsule Contains:
		Fluoxetine HCl20mg
	Diary No. Date of R& I & fee	Dy No. 14427: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective Serotonin Reuptake Inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Wintin capsule by Winlet Pharma
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
		Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each Capsule Contains:
		Fluoxetine (as HCl)20mg

Decision: Approved with following label claim:

Each Capsule Contains:

Fluoxetine (as HCl)...20mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter

M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
Awa Cet 250mg Tablet
Each Film Coated Tablet Contains:
Levetiracetam250mg
Dy No. 14409: 07-03-2019
PKR 20,000/-: 06-03-2019
Other antiepileptics
Form 5
USP
As per SRO
MHRA Approved
Lumark Tablet by Searle
Firm was inspected on 08.01.2019, wherein satisfactory level of GMP
was reported
• Latest GMP inspection report conducted within a period of last three
vears.

127.		ued after submission of updated GMP inspection report by the firm.
	Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
	Brand Name +Dosage Form + Strength	Awa Cet 500mg Tablet
•	Composition	Each Film Coated Tablet Contains: Levetiracetam500mg
-	Diary No. Date of R& I & fee	Dy No. 14410: 07-03-2019
	Diary 100. Date of Rec 1 & 1ce	PKR 20,000/-: 06-03-2019
ŀ	Pharmacological Group	Other antiepileptics
ŀ	Type of Form	Form 5
•	Finished Product Specification	USP
ŀ	Pack size & Demanded Price	As per SRO
-	Approval status of product in Reference	MHRA Approved
ŀ	Regulatory Authorities.	Y 1 m 11 1 2 1
	Me-too status	Lumark Tablet by Searle
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
•	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
ŀ	Decision: Approved.	yours.
		ued after submission of updated GMP inspection report by the firm.
28.	Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
	Brand Name +Dosage Form + Strength	Awa Cet 750mg Tablet
•	Composition	Each Film Coated Tablet Contains:
	Composition	Levetiracetam750mg
	Diary No. Date of R& I & fee	Dy No. 14411: 07-03-2019
	Diary No. Date of R& 1 & Ice	PKR 20,000/-: 06-03-2019
ŀ	Pharmacological Group	Other antiepileptics
ŀ	Type of Form	Form 5
ŀ	Finished Product Specification	USP
ŀ	Pack size & Demanded Price	As per SRO
ŀ	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Lumark Tablet by Searle
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
•	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
-	Decision: Approved.	
129.	Name and address of manufacturer / Applicant	ued after submission of updated GMP inspection report by the firm. M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
•	Brand Name +Dosage Form + Strength	Awa Cet 1000mg Tablet
ŀ	Composition	Each Film Coated Tablet Contains:
	Composition	Levetiracetam1000mg
-	Diary No. Date of R& I & fee	Dy No. 14412: 07-03-2019 PKR 20,000/-: 06-03-2019
-	Pharmacological Group	Other antiepileptics
ľ	Type of Form	Form 5
	Finished Product Specification	USP
ľ	Pack size & Demanded Price	As per SRO
•	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
ŀ	Me-too status	Lumark Tablet by Searle
•	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
		Latest GMP inspection report conducted within a period of last three

130.	Name and address of manufacturer /	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
	Applicant	
	Brand Name +Dosage Form + Strength	U Met 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Metformin HCl200mg
	Diary No. Date of R& I & fee	Dy No. 14422: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Biguanides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		 years. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
		Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for following:	
		rug already approved by DRAP (generic / me-too status) alongwith
	registration number, brand name a	
	 Evidence of approval of applied f 	ormulation in reference regulatory authorities/agencies which were
	adopted by the Registration Board	
		lucted within a period of last three years.
131.	Name and address of manufacturer /	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
	Applicant	11M : 500 - Till :
	Brand Name +Dosage Form + Strength Composition	U Met 500mg Tablet Each Film Coated Tablet Contains:
	Composition	Metformin HCl500mg
	Diary No. Date of R& I & fee	Dy No. 14423: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Biguanides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Glucophage Tablet by Martin Dow
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
	Decision: Approved.	years.
		ued after submission of updated GMP inspection report by the firm.
132.	Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
	Brand Name +Dosage Form + Strength	Co Folanz Tablet 3/25mg
	Composition	Each Capsule Contains:
	2 <u>F</u>	Olanzapine3mg
		Fluoxetine As HCl25mg
	Diary No. Date of R& I & fee	Dy No. 14419: 07-03-2019
	y = 1.2. = 15 01 1.00 1 00 100	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Atypical antipsychotic and a selective serotonin
	T C. P	reuptake inhibitor
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Byflanz capsule by martin dow
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved.	
122		ued after submission of updated GMP inspection report by the firm.
133.	Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
	Brand Name +Dosage Form + Strength	Co Folanz Tablet 6/25mg
	Composition	Each Capsule Contains: Olanzapine6mg Fluoxetine As HCl25mg
	Diary No. Date of R& I & fee	Dy No. 14420: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Atypical antipsychotic and a selective serotonin
	-	reuptake inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Byflanz capsule by martin dow
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three years.
	D	· · ·
	Decision: Approved. • Registration letter will be iss	ued after submission of undated GMP inspection report by the firm.
134.	• Registration letter will be iss Name and address of manufacturer /	ued after submission of updated GMP inspection report by the firm. M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
134.	• Registration letter will be iss Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
134.	• Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg
134.	• Registration letter will be iss Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains:
134.	• Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg
134.	• Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019
134.	Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019
134.	Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019
134.	Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019 Atypical antipsychotic and a selective serotonin
134.	Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019 Atypical antipsychotic and a selective serotonin reuptake inhibitor
134.	• Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019 Atypical antipsychotic and a selective serotonin reuptake inhibitor Form 5
134.	• Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019 Atypical antipsychotic and a selective serotonin reuptake inhibitor Form 5 USP
134.	• Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019 Atypical antipsychotic and a selective serotonin reuptake inhibitor Form 5 USP As per SRO USFDA Approved
134.	• Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019 Atypical antipsychotic and a selective serotonin reuptake inhibitor Form 5 USP As per SRO USFDA Approved Byflanz capsule by martin dow Firm was inspected on 08.01.2019, wherein satisfactory level of GMP
134.	• Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019 Atypical antipsychotic and a selective serotonin reuptake inhibitor Form 5 USP As per SRO USFDA Approved Byflanz capsule by martin dow
134.	• Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved.	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019 Atypical antipsychotic and a selective serotonin reuptake inhibitor Form 5 USP As per SRO USFDA Approved Byflanz capsule by martin dow Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported • Latest GMP inspection report conducted within a period of last three years.
134.	• Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. • Registration letter will be iss Name and address of manufacturer /	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019 Atypical antipsychotic and a selective serotonin reuptake inhibitor Form 5 USP As per SRO USFDA Approved Byflanz capsule by martin dow Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported • Latest GMP inspection report conducted within a period of last three
	• Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. • Registration letter will be iss Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019 Atypical antipsychotic and a selective serotonin reuptake inhibitor Form 5 USP As per SRO USFDA Approved Byflanz capsule by martin dow Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported Latest GMP inspection report conducted within a period of last three years. ued after submission of updated GMP inspection report by the firm. M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
	• Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. • Registration letter will be iss Name and address of manufacturer /	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019 Atypical antipsychotic and a selective serotonin reuptake inhibitor Form 5 USP As per SRO USFDA Approved Byflanz capsule by martin dow Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported • Latest GMP inspection report conducted within a period of last three years. ued after submission of updated GMP inspection report by the firm. M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan U Saprox CR 12.5mg Tablet Each Film Coated Extended Release Tablet Contains:
	• Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. • Registration letter will be iss Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan Co Folanz Tablet 12/25mg Each Capsule Contains: Olanzapine12mg Fluoxetine As HCl25mg Dy No. 14421: 07-03-2019 PKR 20,000/-: 06-03-2019 Atypical antipsychotic and a selective serotonin reuptake inhibitor Form 5 USP As per SRO USFDA Approved Byflanz capsule by martin dow Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported • Latest GMP inspection report conducted within a period of last three years. ued after submission of updated GMP inspection report by the firm. M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan U Saprox CR 12.5mg Tablet

	PKR 20,000/-: 06-03-2019
Pharmacological Group	Selective serotonin reuptake inhibitors
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	USFDA Approved
Regulatory Authorities.	
Me-too status	Seroxat CR Tablet by GSK
GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP
	was reported
Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three
	years.
	Revise your label claim along with submission of full fee as per the
	innovator's product as per following:
	Each enteric, film coated, controlled release tablet contains:
	Paroxetine (as HCl)12.5mg

Each enteric, film coated, controlled release tablet contains:

Paroxetine (as HCl)...12.5mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

Name and address of manufacturer /	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
Applicant	
Brand Name +Dosage Form + Strength	U Saprox CR 25mg Tablet
Composition	Each Film Coated Extended Release Tablet Contains:
	Paroxetine HCl25mg
Diary No. Date of R& I & fee	Dy No. 14416: 07-03-2019
	PKR 20,000/-: 06-03-2019
Pharmacological Group	Selective serotonin reuptake inhibitors
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	USFDA Approved
Regulatory Authorities.	
Me-too status	Seroxat CR Tablet by GSK
GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP
	was reported
Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
	years.
	Revise your label claim along with submission of full fee as per the
	innovator's product as per following:
	Each enteric, film coated, controlled release tablet contains:
	Paroxetine (as HCl)25mg
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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

Decision: Approved with following label claim:

Each enteric, film coated, controlled release tablet contains:

Paroxetine (as HCl)....25mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

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137.	Name and address of manufacturer /	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
	Applicant	
	Brand Name +Dosage Form + Strength	U Saprox CR 37.5mg Tablet
	Composition	Each Film Coated Extended Release Tablet Contains:
		Paroxetine Hcl37.5mg
	Diary No. Date of R& I & fee	Dy No. 14417: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP

Pack size & Demanded Price	As per SRO
Approval status of product in Reference	USFDA Approved
Regulatory Authorities.	
Me-too status	Seroxat CR Tablet by GSK
GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP
Remarks of the Evaluator ³ .	was reported
Remarks of the Evaluator.	• Latest GMP inspection report conducted within a period of last three years.
	Revise your label claim along with submission of full fee as per the
	innovator's product as per following:
	Each enteric, film coated, controlled release tablet contains:
	Paroxetine (as HCl)37.5mg

Each enteric, film coated, controlled release tablet contains:

Paroxetine (as HCl)...37.5mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

138.	Name and address of manufacturer /	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
	Applicant	
	Brand Name +Dosage Form + Strength	Stigamet 50/500mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Sitagliptin50mg
		Metformin HCl500mg
	Diary No. Date of R& I & fee	Dy No. 14413: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Treivamet Tablet by Getz
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP
		was reported
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		years.
		Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each Film Coated Tablet Contains:
		Sitagliptin as Phosphate Monohydrate50mg
		Metformin HCl500mg

Decision: Approved with Innovator's specifications and with following label claim:

Each Film Coated Tablet Contains:

Sitagliptin as Phosphate Monohydrate...50mg

Metformin HCl...500mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

139.	Name and address of manufacturer /	M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan
	Applicant	
	Brand Name +Dosage Form + Strength	Stigamet 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Sitagliptin50mg
		Metformin HCl1000mg
	Diary No. Date of R& I & fee	Dy No. 14414: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications

Pack size & Demanded Price	As per SRO
Approval status of product in Reference	USFDA Approved
Regulatory Authorities.	
Me-too status	Treivamet Tablet by Getz
GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP
	was reported
Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
	years.
	Revise your label claim along with submission of full fee as per the
	innovator's product as per following:
	Each Film Coated Tablet Contains:
	Sitagliptin as Phosphate Monohydrate50mg
	Metformin HCl1000mg

Decision: Approved with Innovator's specifications and with following label claim:

Each Film Coated Tablet Contains:

Sitagliptin as Phosphate Monohydrate...50mg

Metformin HCl...1000mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter

140.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind
	Applicant	Road, Lahore.
	Brand Name +Dosage Form + Strength	Antacid 254/237.5mg/5ml Oral Solution
	Composition	Each 5ml Contains:
		Aluminium Hydroxide254mg
		Magnesium Carbonate237.5mg
	Diary No. Date of R& I & fee	Dy No. 16074: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Could not be confirmed
	Regulatory Authorities.	
	Me-too status	Could not be confirmed
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 11-01-2021.
	Remarks of the Evaluator ³ .	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
		Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm

Decision: Deferred for following:

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

141.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind
	Applicant	Road, Lahore.
	Brand Name +Dosage Form + Strength	Cardil 12.5mg Tablet
	Composition	Each Tablet Contains:
		Carvedilol12.5mg
	Diary No. Date of R& I & fee	Dy No. 16339: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	

	Me-too status	Carveda tablet by Ferozesons
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
142.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind
172.	Applicant	Road, Lahore.
	Brand Name +Dosage Form + Strength	Cardil 25mg Tablet
	Composition	Each Tablet Contains:
	Composition	
	D'an Na Data (DO LO Car	Carvedilol25mg
	Diary No. Date of R& I & fee	Dy No. 16344: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	
	Regulatory Authorities.	MHRA Approved
	Me-too status	Carveda tablet by Ferozesons
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 11-01-2021.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	<u>I</u>
142		M/s Tricon Dhouses continues (Det) I 4d 9 has Tholon Deimind
143.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind
	Applicant	Road, Lahore.
	Brand Name +Dosage Form + Strength	Ibabrine 5mg Tablet
	Composition	Each Tablet Contains:
		Ivabradine (as HCl)5mg
	Diary No. Date of R& I & fee	Dy No. 16078: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	MilitarApproved
	Me-too status	Ivadine Tablet by Pharmevo
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 11-01-2021.
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
	Remarks of the Evaluator .	innovator's product as per following:
		Each Film Coated Tablet Contains:
		Ivabradine (as HCl)5mg
	Designer Approved with I	pecifications and with following label claim:
	Each Film Coated Tablet Cont	
		ams:
	Ivabradine (as HCl)5mg	
		revision of formulation from uncoated tablet to film coated tablet as
	per notification No.F.7-11/2012-	
144.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind
	Applicant	Road, Lahore.
	Brand Name +Dosage Form + Strength	Ibabrine 7.5mg Tablet
	Composition	Each Tablet Contains:
		Ivabradine Hcl7.5mg
	Diary No. Date of R& I & fee	Dy No. 16077: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	
		Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	<u> </u>	

	Me-too status	Ivadine Tablet by Pharmevo		
	GMP status	Firm has submitted copy of GMP certificate issued on the basis		
		of inspection dated 11-01-2021.		
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the		
	Temans of the Evaluator .	innovator's product as per following:		
		Each Film Coated Tablet Contains:		
		Ivabradine (as HCl)7.5mg		
	Decision: Approved with Innovator's s	pecifications and with following label claim:		
	Each Film Coated Tablet Cont			
	Ivabradine (as HCl)7.5mg			
	• Firm shall submit 7,500/- fee for	revision of formulation from uncoated tablet to film coated tablet as		
	per notification No.F.7-11/2012-I	3&A/DRAP dated 07-05-2021.		
145.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind		
	Applicant	Road, Lahore.		
	Brand Name +Dosage Form + Strength	Sparmid 500mg Tablet		
	Composition	Each Tablet Contains:		
		Nitazoxanide500mg		
	Diary No. Date of R& I & fee	Dy No. 16364: 07-03-2019		
	N 1 1 1 G	PKR 20,000/-: 06-03-2019		
	Pharmacological Group	Other agents against amoebiasis and other protozoal diseases		
	Type of Form	Form 5		
	Finished Product Specification	Firm has claimed in house specifications		
	Pack size & Demanded Price	As per SRO		
	Approval status of product in Reference	USFDA Approved		
	Regulatory Authorities.	D''1. T.111. MVD DI		
	Me-too status GMP status	Diranide Tablet by MKB Pharma		
	GMP status	Firm has submitted copy of GMP certificate issued on the basis		
		of inspection dated 11-01-2021.		
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the		
		innovator's product as per following:		
		Each Film Coated Tablet Contains:		
	Designer Approved with Innovator's s	Nitazoxanide500mg		
	Decision: Approved with Innovator's specifications and with following label claim:			
	Nitazoxanide500mg	Each Film Coated Tablet Contains:		
	9	revision of formulation from uncoated tablet to film coated tablet as		
	• Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.			
146.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind		
	Applicant	Road, Lahore.		
	Brand Name +Dosage Form + Strength	Ronrox 1mg Tablet		
	Composition	Each Tablet Contains:		
	1	Ropinirole (as HCl)1mg		
	Diary No. Date of R& I & fee	Dy No. 16064: 07-03-2019		
		PKR 20,000/-: 07-03-2019		
	Pharmacological Group	Dopamine agonists		
	Type of Form	Form 5		
	Finished Product Specification	USP		
	Pack size & Demanded Price	As per SRO		
	Approval status of product in Reference	MHRA Approved		
	Regulatory Authorities.			
	Ma too status	Domining of Tohlat by Mass Dhamas		

Ropinirole Tablet by Mass Pharma

of inspection dated 11-01-2021.

Ropinirole (as HCl)...1mg

innovator's product as per following: Each Film Coated Tablet Contains:

Firm has submitted copy of GMP certificate issued on the basis

• Revise your label claim along with submission of 7500 fee as per the

Decision: Approved with following label claim: Each Film Coated Tablet Contains:

Ropinirole (as HCl)...1mg

Me-too status

Remarks of the Evaluator³.

GMP status

	• Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-F	revision of formulation from uncoated tablet to film coated tablet as 8&A/DRAP dated 07-05-2021.
147.		M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.
ì	Brand Name +Dosage Form + Strength	Ronrox 2mg Tablet
	Composition	Each Tablet Contains:
	Composition	Ropinirole (as HCl)2mg
	Diary No. Date of R& I & fee	Dy No. 16065: 07-03-2019
	. ,	PKR 20,000/-: 07-03-2019
	Pharmacological Group	Dopamine agonists
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ropinirole Tablet by Mass Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
		innovator's product as per following:
		Each Film Coated Tablet Contains:
		Ropinirole (as HCl)2mg
	Decision: Approved with following laboration	
	Each Film Coated Tablet Cont	tains:
	Ropinirole (as HCl)2mg	
	per notification No.F.7-11/2012-I	
148.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind
	Applicant	Road, Lahore.
	Brand Name +Dosage Form + Strength	Tarblend Topical Solution
	Composition	Each ml Contains:
	D'an Na Data (D.O. L.O. C.)	Polytar1%
	Diary No. Date of R& I & fee	Dy No. 16055: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	keratoplastics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Could not be confirmed
	Regulatory Authorities.	Could not be commined
	Me-too status	Could not be confirmed
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 11-01-2021.
	Remarks of the Evaluator ³ .	Evidence of approval of applied formulation in reference regulatory
	Remarks of the Evaluator.	authorities/agencies which were adopted by the Registration Board in
		its 275th meeting.
		Evidence of applied formulation/drug already approved by DRAP
		(generic / me-too status) alongwith registration number, brand name
		and name of firm
	Decision: Deferred for following:	
	• Evidence of applied formulation/d	rug already approved by DRAP (generic / me-too status) alongwith
	registration number, brand name a	
	 Evidence of approval of applied f adopted by the Registration Board 	formulation in reference regulatory authorities/agencies which were in its 275 th meeting.
149.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind
	Applicant	Road, Lahore.
	Brand Name +Dosage Form + Strength	Mimal Z 15mg/3ml Injection
	Composition	Each 3ml ampoule Contains:
		Midazolam (as HCl)15mg
	Diary No. Date of R& I & fee	Dy No. 16085: 07-03-2019
		PKR 20,000/-: 07-03-2019

	Pharmacological Group	Benzodiazepine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Midza Injection by ameer Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 11-01-2021.
	Remarks of the Evaluator ³ .	Firm has submitted letter of renewal of DML dated 10-08-2015
		which specifies Liquid injection ampoule (psychotropic) section.
	Decision: Approved.	
150.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind
	Applicant	Road, Lahore.
	Brand Name +Dosage Form + Strength	Glitamin 1/500mg Tbalet
	Composition	Each Tablet Contains:
		Rosiglitazone (as Maleate)1mg
		Metformin HCl500mg
	Diary No. Date of R& I & fee	Dy No. 16083: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Rosiform Tablet by CCL
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 11-01-2021.
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
		innovator's product as per following:
		Each Film Coated Tablet Contains:
		Rosiglitazone (as Maleate)1mg
		Metformin HCl500mg
		pecifications and with following label claim:
	Each Film Coated Tablet Cont	
	Rosiglitazone (as Maleate)1r	ng
	Metformin HCl500mg	
		revision of formulation from uncoated tablet to film coated tablet as
	per notification No.F.7-11/2012-E	
151.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind
	Applicant	Road, Lahore.
	Brand Name +Dosage Form + Strength	Glitamin 2/500mg Tablet
	Composition	Each Tablet Contains:
		Rosiglitazone (as Maleate)2mg
	Diary No. Date of R& I & fee	Metformin HCl500mg Dy No. 16067: 07-03-2019
	Diary No. Date of R& 1 & fee	PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Rosiform Tablet by CCL
	GMP status	
	OWIF STATUS	Firm has submitted copy of GMP certificate issued on the basis
	Demonder Cale F 1 4 2	of inspection dated 11-01-2021.
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
		innovator's product as per following:
		Each Film Coated Tablet Contains: Rosiglitazone (as Maleate)2mg

	specifications and with following label claim:		
Each Film Coated Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin HCl500mg			
			r revision of formulation from uncoated tablet to film coated tablet
		per notification No.F.7-11/2012-	
Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind		
Applicant	Road, Lahore.		
Brand Name +Dosage Form + Strength	Glitamin 4/500mg Tablet		
Composition	Each Tablet Contains:		
	Rosiglitazone (as Maleate)4mg		
Diary No. Date of R& I & fee	Metformin HCl500mg Dy No. 16070: 07-03-2019		
Diary No. Date of R& 1 & fee	PKR 20,000/-: 07-03-2019		
Dharmacalogical Group	Antidiabetic		
Pharmacological Group	Form 5		
Type of Form			
Finished Product Specification	Firm has claimed in house specifications		
Pack size & Demanded Price	As per SRO		
Approval status of product in Reference	USFDA Approved		
Regulatory Authorities. Me-too status	Posiform Tablet by CCI		
	Rosiform Tablet by CCL		
GMP status	Firm has submitted copy of GMP certificate issued on the basis		
	of inspection dated 11-01-2021.		
Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the		
	innovator's product as per following:		
	Each Film Coated Tablet Contains:		
	Rosiglitazone (as Maleate)4mg		
	Metformin HCl500mg		
Decision: Approved with Innovator's s	specifications and with following label claim:		
Decision: Approved with Innovator's s Each Film Coated Tablet Con			
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4	tains:		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg	tains: mg		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for	tains: mg revision of formulation from uncoated tablet to film coated tablet a		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1	tains: mg revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021.		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1 Name and address of manufacturer /	tains: mg revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1 Name and address of manufacturer / Applicant	tains: mg revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1 Name and address of manufacturer / Applicant	tains: mg revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains:		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	revision of formulation from uncoated tablet to film coated tablet a 8&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	revision of formulation from uncoated tablet to film coated tablet a 8&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications As per SRO		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications As per SRO USFDA Approved		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications As per SRO USFDA Approved Rosiform Tablet by CCL		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1 Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications As per SRO USFDA Approved Rosiform Tablet by CCL		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications As per SRO USFDA Approved Rosiform Tablet by CCL		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications As per SRO USFDA Approved Rosiform Tablet by CCL Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications As per SRO USFDA Approved Rosiform Tablet by CCL Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications As per SRO USFDA Approved Rosiform Tablet by CCL Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. Revise your label claim along with submission of 7500 fee as per the second content of the submission o		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications As per SRO USFDA Approved Rosiform Tablet by CCL Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains:		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	revision of formulation from uncoated tablet to film coated tablet as B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications As per SRO USFDA Approved Rosiform Tablet by CCL Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. Revise your label claim along with submission of 7500 fee as per thinnovator's product as per following:		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	revision of formulation from uncoated tablet to film coated tablet a B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications As per SRO USFDA Approved Rosiform Tablet by CCL Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rosiglitazone (as Maleate)2mg		
Each Film Coated Tablet Con Rosiglitazone (as Maleate)4 Metformin HCl500mg • Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	tains: mg revision of formulation from uncoated tablet to film coated tablet as B&A/DRAP dated 07-05-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Glitamin plus 2mg/1000mg Tablet Each Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin Hcl1000mg Dy No. 16073: 07-03-2019 PKR 20,000/-: 07-03-2019 Antidiabetic Form 5 Firm has claimed in house specifications As per SRO USFDA Approved Rosiform Tablet by CCL Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rosiglitazone (as Maleate)2mg Metformin HC11000mg specifications and with following label claim:		

	• Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I	3&A/DRAP dated 07-05-2021.
154.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind
	Applicant	Road, Lahore.
	Brand Name +Dosage Form + Strength	Glitamin plus 4mg/1000mg Tablet
	Composition	Each Tablet Contains:
	Composition	
		Rosiglitazone (as Maleate)4mg
		Metformin HC11000mg
	Diary No. Date of R& I & fee	Dy No. 16095: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	Col Bri rippioved
	Me-too status	Rosiform Tablet by CCL
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 11-01-2021.
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
		innovator's product as per following:
		Each Film Coated Tablet Contains:
		Rosiglitazone (as Maleate)4mg
		Metformin HCl1000mg
	Designary Annuary of with Innervator's a	pecifications and with following label claim:
	 Metformin HCl1000mg Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I 	revision of formulation from uncoated tablet to film coated tablet as 3&A/DRAP dated 07-05-2021.
155.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind
	Applicant	Road, Lahore.
	Brand Name +Dosage Form + Strength	Holip 5mg/ml Injection
	Composition	Each 1ml ampoule Contains:
	Composition	
	Diamy No. Data of D % I % for	Haloperidol (as Lactate)5mg
	Diary No. Date of R& I & fee	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019
	-	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics
	Pharmacological Group Type of Form	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5
	Pharmacological Group Type of Form Finished Product Specification	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics
	Pharmacological Group Type of Form	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5
	Pharmacological Group Type of Form Finished Product Specification	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO
	Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP
	Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved
	Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma
	Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis
	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	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma
	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 ³ .	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis
	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 ³ . Decision: Approved.	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
156.	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 ³ . Decision: Approved. Name and address of manufacturer /	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind
156.	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 ³ . Decision: Approved. Name and address of manufacturer / Applicant	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.
156.	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 ³ . Decision: Approved. Name and address of manufacturer /	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Nitanide 100mg Dry Powder suspension
156.	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 ³ . Decision: Approved. Name and address of manufacturer / Applicant	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.
156.	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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Nitanide 100mg Dry Powder suspension
156.	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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Nitanide 100mg Dry Powder suspension Each 5ml Contains: Nitazoxanide100gm
156.	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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Nitanide 100mg Dry Powder suspension Each 5ml Contains: Nitazoxanide100gm Dy No. 16081: 07-03-2019
156.	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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Nitanide 100mg Dry Powder suspension Each 5ml Contains: Nitazoxanide100gm Dy No. 16081: 07-03-2019 PKR 20,000/-: 07-03-2019
156.	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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Nitanide 100mg Dry Powder suspension Each 5ml Contains: Nitazoxanide100gm Dy No. 16081: 07-03-2019 PKR 20,000/-: 07-03-2019 Other agents against amoebiasis and other protozoal diseases
56.	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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Nitanide 100mg Dry Powder suspension Each 5ml Contains: Nitazoxanide100gm Dy No. 16081: 07-03-2019 PKR 20,000/-: 07-03-2019 Other agents against amoebiasis and other protozoal diseases Form 5
156.	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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Nitanide 100mg Dry Powder suspension Each 5ml Contains: Nitazoxanide100gm Dy No. 16081: 07-03-2019 PKR 20,000/-: 07-03-2019 Other agents against amoebiasis and other protozoal diseases Form 5 Firm has claimed in house specifications
156.	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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Nitanide 100mg Dry Powder suspension Each 5ml Contains: Nitazoxanide100gm Dy No. 16081: 07-03-2019 PKR 20,000/-: 07-03-2019 Other agents against amoebiasis and other protozoal diseases Form 5 Firm has claimed in house specifications As per SRO
156.	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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Haloperidol (as Lactate)5mg Dy No. 16072: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Ceretek Injection by Schazoo Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore. Nitanide 100mg Dry Powder suspension Each 5ml Contains: Nitazoxanide100gm Dy No. 16081: 07-03-2019 PKR 20,000/-: 07-03-2019 Other agents against amoebiasis and other protozoal diseases Form 5 Firm has claimed in house specifications

	Me-too status	Diranide Tablet by MKB Pharma
1	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 11-01-2021.
	Remarks of the Evaluator ³ .	ap
	Decision: Approved with Innovator's s	pecifications.
157.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind
	Applicant	Road, Lahore.
	Brand Name +Dosage Form + Strength	Venlox 75mg Tablet
	Composition	Each Tablet Contains:
		Venlafexine (as HCl)75mg
	Diary No. Date of R& I & fee	Dy No. 16062: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Velax Tablet by Schazoo Zaka
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 11-01-2021.
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
		innovator's product as per following:
		Each Film Coated Tablet Contains:
		Venlafexine (as HCl)75mg
	Decision: Approved with following labor	
	Each Film Coated Tablet Cont	ains:
	Venlafexine (as HCl)75mg	
		revision of formulation from uncoated tablet to film coated tablet as
	per notification No.F.7-11/2012-I	0&A/DRAP dated 07-05-2021.
158	Name and address of manufacturar /	M/s Trigon Pharmacouticals (Pyt) I td & km Thokar Paiwind
158.	Name and address of manufacturer /	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.
158.	Applicant	Road, Lahore.
158.	Applicant Brand Name +Dosage Form + Strength	
158.	Applicant	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains:
158.	Applicant Brand Name +Dosage Form + Strength Composition	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg
158.	Applicant Brand Name +Dosage Form + Strength	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains:
158.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019
158.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics
158.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019
158.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP
158.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5
158.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO
158.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma
158.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis
158.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma
158.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved.	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis
158.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad Zolret 2.5mg Tablet
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad Zolret 2.5mg Tablet Each Tablet Contains:
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad Zolret 2.5mg Tablet Each Tablet Contains: Letrozole2.5mg
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad Zolret 2.5mg Tablet Each Tablet Contains: Letrozole2.5mg Dy No. 13949: 07-03-2019
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad Zolret 2.5mg Tablet Each Tablet Contains: Letrozole2.5mg Dy No. 13949: 07-03-2019 PKR 20,000/-: 06-03-2019
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad Zolret 2.5mg Tablet Each Tablet Contains: Letrozole2.5mg Dy No. 13949: 07-03-2019 PKR 20,000/-: 06-03-2019 Aromatase inhibitors
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad Zolret 2.5mg Tablet Each Tablet Contains: Letrozole2.5mg Dy No. 13949: 07-03-2019 PKR 20,000/-: 06-03-2019 Aromatase inhibitors Form 5
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad Zolret 2.5mg Tablet Each Tablet Contains: Letrozole2.5mg Dy No. 13949: 07-03-2019 PKR 20,000/-: 06-03-2019 Aromatase inhibitors Form 5 USP
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad Zolret 2.5mg Tablet Each Tablet Contains: Letrozole2.5mg Dy No. 13949: 07-03-2019 PKR 20,000/-: 06-03-2019 Aromatase inhibitors Form 5 USP As per SRO
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Road, Lahore. Fluzex 25mg/ml Injection Each ml Contains: Fluphenazine Deconate25mg Dy No. 16347: 07-03-2019 PKR 20,000/-: 07-03-2019 Antipsychotics Form 5 USP As per SRO USFDA Approved Adecate 25mg/ml Injection by Adamjee Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021. M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad Zolret 2.5mg Tablet Each Tablet Contains: Letrozole2.5mg Dy No. 13949: 07-03-2019 PKR 20,000/-: 06-03-2019 Aromatase inhibitors Form 5 USP

Femara Tablet by Novartis
Firm has submitted copy of GMP certificate issued by Additional
Director DRAP, Islamabad dated 31-07-2019. The GMP certificate was
granted based on inspection dated 11-02-2019. The GMP certificate is
valid till 10-02-2022.
• Latest GMP inspection report conducted within a period of last three
years.
• Revise your label claim along with submission of 7500 fee as per the
innovator's product as per following:
Each Film Coated Tablet Contains:
Letrozole2.5mg

Decision: Registration Board approved registration of product with following label claim in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.

Each Film Coated Tablet Contains:

Letrozole...2.5mg

• Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Name and address of manufacturer /	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle,
Applicant	Kahuta Road, Islamabad
Brand Name +Dosage Form + Strength	Zorid 100mg Tablet
Composition	Each Tablet Contains:
	Levosulpride100mg
Diary No. Date of R& I & fee	Dy No. 13956: 07-03-2019
	PKR 20,000/-: 06-03-2019
Pharmacological Group	Antipsychotic
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	Could not be confirmed
Regulatory Authorities.	
Me-too status	Medpride tablet by Medpharm Research Lab
GMP status	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad dated 31-07-2019. The GMP certificate was granted based on inspection dated 11-02-2019. The GMP certificate is valid till 10-02-2022.
Remarks of the Evaluator ³ .	 Latest GMP inspection report conducted within a period of last three years. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board
Desisione Defensed for following submit	in its 275th meeting.

Decision: Deferred for following submissions:

 Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.

• Latest GMP inspection report conducted within a period of last three years.

161.	Name and address of manufacturer /	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle,
	Applicant	Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Gpenta 50mg Tablet
	Composition	Each SR Tablet Contains:
		Tapentadol50mg
	Diary No. Date of R& I & fee	Dy No. 13951: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Analgesics, opioids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Could not be confirmed
	GMP status	Firm has submitted copy of GMP certificate issued by Additional
		Director DRAP, Islamabad dated 31-07-2019. The GMP certificate was

	granted based on inspection dated 11-02-2019. The GMP certificate is valid till 10-02-2022.
Remarks of the Evaluator ³ .	 Latest GMP inspection report conducted within a period of last three years. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5D along with differential fee
	 Stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting. Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Prolonged Release Tablet Contains: Tapentadol (as maleate hemihydrate)50mg

Decision: Deferred for following submissions:

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5D along with differential fee
- Stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting.
- Latest GMP inspection report conducted within a period of last three years.
- Revision of the formulation and label claim as per the innovator's product along with submission of full fee of registration.

162.	Name and address of manufacturer /	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle,
	Applicant	Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Gpenta 100mg Tablet
	Composition	Each SR Tablet Contains:
		Tapentadol100mg
	Diary No. Date of R& I & fee	Dy No. 13949: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Analgesics, opioids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Could not be confirmed
	GMP status	Firm has submitted copy of GMP certificate issued by Additional
		Director DRAP, Islamabad dated 31-07-2019. The GMP certificate was
		granted based on inspection dated 11-02-2019. The GMP certificate is
ŀ	D 1 C1 D 1 2	valid till 10-02-2022.
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three years.
		Evidence of applied formulation/drug already approved by DRAP
		(generic / me-too status) alongwith registration number, brand name
		and name of firm or else application on Form 5D along with
		differential fee
		Stability study data of three batches as per the guidelines and
		checklist approved by Registration Board in its 312 th meeting.
		Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each Film Coated Prolonged Release Tablet Contains:
		Tapentadol (as maleate hemihydrate)100mg

Decision: Deferred for following submissions:

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5D along with differential fee
- Stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting.
- Latest GMP inspection report conducted within a period of last three years.
- Revision of the formulation and label claim as per the innovator's product along with submission of full fee of registration.

163.	Name and address of manufacturer / Applicant	M/s Wellborne Pharmachem & Biologicals. Plot No. 51/1, 52/2, Phase I & II, Hattar Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Fenbro-67 mg Capsule
	Composition	Each Capsule Contains:
	Composition	Fenofibrate67mg
	Diary No. Date of R& I & fee	Dy No. 16814: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Lipid modifying agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	initial 1 ipplo (ou
	Me-too status	Lebirat capsule by Fynk Pharma
	GMP status	Last GMP inspection was conducted on 27-6-2018
		concluded good GMP.
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		years.
	Decision: Approved.	y carb.
		ued after submission of updated GMP inspection report by the firm.
164.	Name and address of manufacturer /	M/s Wellborne Pharmachem & Biologicals. Plot No. 51/1, 52/2,
10	Applicant	Phase I & II, Hattar Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Solobron 5mg Tablet
	Composition	Each Film Coated Tablet Contains:
	Composition	Solifenacin Succinate5mg
	Diary No. Date of R& I & fee	Dy No. 16813: 07-03-2019
	Bury 100. But of fee fee fee	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	Milita Approved
	Me-too status	Solif Tablet by Global
	GMP status	Last GMP inspection was conducted on 27-6-2018
		concluded good GMP.
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		years.
	Decision: Approved with Innovator's s	·
		ed after submission of updated GMP inspection report by the firm.
		or revision of specifications as per notification No.F.7-11/2012-
	B&A/DRAP dated 07-05-2021.	<u>*</u>
165.	Name and address of manufacturer /	M/s Wellborne Pharmachem & Biologicals. Plot No. 51/1, 52/2,
	Applicant	Phase I & II, Hattar Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Solobron 10mg Tablet
	Composition	Each Film Coated Tablet Contains:
	-	Solifenacin Succinate10mg
	Diary No. Date of R& I & fee	Dy No. 16815: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Solif Tablet by Global
	GMP status	Last GMP inspection was conducted on 27-6-2018
		concluded good GMP.
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
	· · · · · · · · · · · · · · · · · · ·	years.
	Decision: Approved with Innovator's s	·
-		

	Registration letter will be issue	ed after submission of updated GMP inspection report by the firm.
	•	or revision of specifications as per notification No.F.7-11/2012-
	B&A/DRAP dated 07-05-2021.	
166.	Name and address of manufacturer /	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd.
	Applicant	Plot # 108, R-2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Spacmic 80/80 mg Tablet
	Composition	Each Sugar Coated Tablet Contains:
		Hydrated Phloroglucinol80mg
	D' N D (CD0 L0 C	Trimethyl Phloroglucinol80mg
	Diary No. Date of R& I & fee	Dy No. 16934: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antispasmodic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Spasfon, coated tablet by M/s Teva Sante, ANSM France
	Regulatory Authorities.	Approved.
	Me-too status	Gluwix Tablet by Wnsfield
	GMP status	The firm M/s Welmed Pharmaceutical Industries was inspected on 17-09-2020 and conclusion of inspection was: Based on the area inspected,
		the people met and documentation reviewed and considering the findings
		of inspection, M/s Welmed Pharmaceutical Industries (Pvt.) Ltd.
		Gadoon-Swabi is considered to be operating at fair level of compliance
		with GMP guidelines as per Drug Act, 1976 and rules framed thereunder.
	Remarks of the Evaluator ³ .	
	Decision: Approved with Innovator's s	pecifications.
	• Firm shall submit 7,500/- fee fo	or revision of specifications as per notification No.F.7-11/2012-
	B&A/DRAP dated 07-05-2021.	
167.	Name and address of manufacturer /	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial
	Applicant	Estate, Gujranwala Cantt.
	Brand Name +Dosage Form + Strength	Disten 5/80mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Amlodipine Besylate5mg Valsartan80mg
	Diary No. Date of R& I & fee	Dy No. 16960: 07-03-2019
	Dialy 110. Date of fee 1 ce fee	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Exforge Tablet by Novartis
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
	Remarks of the Evaluator ³ .	Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each Film Coated Tablet Contains:
		Amlodipine Besylate Eq. To Amlodipine5mg
		Valsartan80mg
	Decision: Approved with following labor	
	Each Film Coated Tablet Amlodipine Besylate Eq.	
	Valsartan80mg	10 / MinourphicSing
		s. 30,000/- for correction/pre-approval change in product label claim
	as per notification No.F.7-11/2	012-B&A/DRAP dated 07-05-2021, before issuance of registration
1/0	letter.	M/s Welmink Discuss cond-to-by Decision C.E. D. 17.1.4.1.
168.	Name and address of manufacturer /	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial
	Applicant Brand Name +Dosage Form + Strength	Estate, Gujranwala Cantt. L zid 600mg Tablet
	Composition	Each Film Coated Tablet Contains:
	Composition	Linezolid600mg
		Linezonaooonig

	Diary No. Date of R& I & fee	Dy No. 16961: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antibacterials
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Nezkil Tablet by S.J&G Fazul Ellahie
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of
		inspection dated 28-07-2022
	Remarks of the Evaluator ³ .	
	Decision: Approved with Innovator's s	pecifications.
	• Firm shall submit 7,500/- fee for	or revision of specifications as per notification No.F.7-11/2012-
	B&A/DRAP dated 07-05-2021	
169.	Name and address of manufacturer /	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial
	Applicant	Estate, Gujranwala Cantt.
	Brand Name +Dosage Form + Strength	Otenz 5mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Olanzapine5mg
	Diary No. Date of R& I & fee	Dy No. 16965: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Olpine Tablet by Fynk Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of
		inspection dated 28-07-2022
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
170.		M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial
170.	Decision: Approved. Name and address of manufacturer / Applicant	Estate, Gujranwala Cantt.
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Estate, Gujranwala Cantt. Otenz 10mg Tablet
170.	Decision: Approved. Name and address of manufacturer / Applicant	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains:
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma Firm has submitted copy of GMP certificate issued on the basis of
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma Firm has submitted copy of GMP certificate issued on the basis of
	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved.	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
170.	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer /	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022 M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial
	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022 M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022 M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt. Dlemet Plus 20/5mg Tablet
	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022 M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt. Dlemet Plus 20/5mg Tablet Each Film Coated Tablet Contains:
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022 M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt. Dlemet Plus 20/5mg Tablet Each Film Coated Tablet Contains: Olmesartan20mg
	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022 M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt. Dlemet Plus 20/5mg Tablet Each Film Coated Tablet Contains: Olmesartan20mg Amlodipine5mg
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022 M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt. Dlemet Plus 20/5mg Tablet Each Film Coated Tablet Contains: Olmesartan20mg Amlodipine5mg Dy No. 16969: 07-03-2019
	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022 M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt. Dlemet Plus 20/5mg Tablet Each Film Coated Tablet Contains: Olmesartan20mg Amlodipine5mg Dy No. 16969: 07-03-2019 PKR 20,000/-: 06-03-2019
	Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Estate, Gujranwala Cantt. Otenz 10mg Tablet Each Film Coated Tablet Contains: Olanzapine10mg Dy No. 16966: 07-03-2019 PKR 20,000/-: 06-03-2019 Antipsychotics Form 5 USP As per SRO MHRA Approved Olpine Tablet by Fynk Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022 M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt. Dlemet Plus 20/5mg Tablet Each Film Coated Tablet Contains: Olmesartan20mg Amlodipine5mg Dy No. 16969: 07-03-2019

Form 5
USP
As per SRO
USFDA Approved.
Baritec-A Tablets by Barrett Hodgson
Firm has submitted copy of GMP certificate issued on the basis of
inspection dated 28-07-2022
• Revise your label claim along with submission of full fee as per the
innovator's product as per following:
Each Film Coated Tablet Contains:
Amlodipine Besylate Eq. To Amlodipine5mg
Olmesartan Medoxomil20mg

Each Film Coated Tablet Contains:

Amlodipine Besylate Eq. To Amlodipine...5mg

Olmesartan Medoxomil...20mg

• The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

. Name and address of manufacturer /	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial
Applicant	Estate, Gujranwala Cantt.
Brand Name +Dosage Form + Strength	Dlemet Plus 20/10mg Tablet
Composition	Each Film Coated Tablet Contains:
	Olmesartan20mg
	Amlodipine10mg
Diary No. Date of R& I & fee	Dy No. 16970: 07-03-2019
	PKR 20,000/-: 06-03-2019
Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel
	blockers
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	USFDA Approved.
Regulatory Authorities.	
Me-too status	Baritec-A Tablets by Barrett Hodgson
GMP status	Firm has submitted copy of GMP certificate issued on the basis of
	inspection dated 28-07-2022
Remarks of the Evaluator ³ .	• Revise your label claim along with submission of full fee as per the
	innovator's product as per following:
	Each Film Coated Tablet Contains:
	Amlodipine Besylate Eq. To Amlodipine10mg
	Olmesartan Medoxomil20mg
	·

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:

Amlodipine Besylate Eq. To Amlodipine...10mg

Olmesartan Medoxomil...20mg

• The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

173.	Name and address of manufacturer /	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial
	Applicant	Estate, Gujranwala Cantt.
	Brand Name +Dosage Form + Strength	Dlemet Plus 40/5mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Olmesartan40mg
		Amlodipine5mg
	Diary No. Date of R& I & fee	Dy No. 16971: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel
		blockers
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved.
	Regulatory Authorities.	
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of
	_	inspection dated 28-07-2022
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each Film Coated Tablet Contains:
		Amlodipine Besylate Eq. To Amlodipine5mg
	Decision: Approved with following labe	Olmesartan Medoxomil40mg
	Each Film Coated Tablet	
	Amlodipine Besylate Eq.	
	Olmesartan Medoxomil	
	 The firm shall submit fee of Rs 	3. 30,000/- for correction/pre-approval change in product label claim
	as per notification No.F.7-11/2	012-B&A/DRAP dated 07-05-2021, before issuance of registration
	letter.	
174.	Name and address of manufacturer /	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial
	Applicant	Estate, Gujranwala Cantt.
	Brand Name +Dosage Form + Strength	Glitamet 50/500mg Tablet Each Film Coated Tablet Contains:
	Composition	Vildagliptin50mg
		Metformin HCl500mg
	Diary No. Date of R& I & fee	Dy No. 16959: 07-03-2019
	21411 1 101 2 410 01 1100 1 00 100	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	TGA Approved
	Regulatory Authorities.	
	Me-too status	Galmet Tablet by Vision Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
	Remarks of the Evaluator ³ .	inspection dated 20-07-2022
	Decision: Approved with Innovator's s	pecifications.
		or revision of specifications as per notification No.F.7-11/2012-
	B&A/DRAP dated 07-05-2021.	
175.	Name and address of manufacturer /	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II,
	Applicant	Industrial Estate Hattar,
	Brand Name +Dosage Form + Strength	Varbet 16mg Tablet
	Composition	Each Tablet Contains: Betahistine Dihydrochloride16mg
	Diary No. Date of R& I & fee	Dy No. 16167: 07-03-2019
	Blary 140. Bate of Ree I ee Ice	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	C Tell (1 - All) (1
	Me-too status	Serc Tablet by Abbott The firm has submitted conv of GMP Cortificate No. F.11. 76/2022
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator ³ .	DIGH 07 155000 OH 10/00/2022 YUNU HII JU/03/2022.
	Decision: Approved.	
176.	Name and address of manufacturer /	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II,
	Applicant	Industrial Estate Hattar,
	Brand Name +Dosage Form + Strength	Varbet 24mg Tablet
	Composition	Each Tablet Contains:
		Betahistine Dihydrochloride24mg

	Diam No Data of DO I O for	D. N. 16169, 07 02 2010
	Diary No. Date of R& I & fee	Dy No. 16168: 07-03-2019 PKR 20,000/-: 06-03-2019
	Dhama and ariant Carre	
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Serc Tablet by Abbott
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-
		DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
177.	Name and address of manufacturer /	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II,
	Applicant	Industrial Estate Hattar,
	Brand Name +Dosage Form + Strength	Varbet 48mg Tablet
	Composition	Each Tablet Contains:
		Betahistine Dihydrochloride48mg
	Diary No. Date of R& I & fee	Dy No. 16169: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Serc Tablet by Abbott
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-
		DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
	N/	M/g Wolwyd Dhompoguticals Dlot #2 Dlock A Dhose I II
178.	Name and address of manufacturer /	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II,
178.	Applicant	Industrial Estate Hattar,
178.	Applicant Brand Name +Dosage Form + Strength	Industrial Estate Hattar, Carvol 6.25mg Tablet
178.	Applicant	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains:
178.	Applicant Brand Name +Dosage Form + Strength Composition	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg
178.	Applicant Brand Name +Dosage Form + Strength	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-
1/8.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
1/8.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the
1/8.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following:
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains:
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Carvedilol6.25mg
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labely	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Carvedilol6.25mg
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laborator and the state of	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Carvedilol6.25mg
1/8.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laborator and the contains: Carvedilol6.25mg	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Carvedilol6.25mg el claim:
178.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labe Each Tablet Contains: Carvedilol6.25mg • Firm shall submit 7,500/- fee for residuation	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Carvedilol6.25mg el claim:
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labe Each Tablet Contains: Carvedilol6.25mg Firm shall submit 7,500/- fee for r per notification No.F.7-11/2012-B.	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Carvedilol6.25mg el claim: evision of formulation from film coated tablet to uncoated tablet as &A/DRAP dated 07-05-2021.
179.	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laberator and the Each Tablet Contains: Carvedilol6.25mg Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer /	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Carvedilol6.25mg el claim: evision of formulation from film coated tablet to uncoated tablet as &A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II,
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laberator and the Each Tablet Contains: Carvedilol6.25mg Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Carvedilol6.25mg el claim: evision of formulation from film coated tablet to uncoated tablet as &A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labe Each Tablet Contains: Carvedilol6.25mg Firm shall submit 7,500/- fee for r per notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Carvedilol6.25mg el claim: evision of formulation from film coated tablet to uncoated tablet as &A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, FBX 80mg Tablet
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laberator and the Each Tablet Contains: Carvedilol6.25mg Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Carvedilol6.25mg el claim: evision of formulation from film coated tablet to uncoated tablet as &A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, FBX 80mg Tablet Each Film Coated Tablet Contains:
	Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labe Each Tablet Contains: Carvedilol6.25mg Firm shall submit 7,500/- fee for r per notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Industrial Estate Hattar, Carvol 6.25mg Tablet Each Film Coated Tablet Contains: Carvedilol6.25mg Dy No. 16174: 07-03-2019 PKR 20,000/-: 06-03-2019 Alpha and beta blocking agents Form 5 USP As per SRO MHRA Approved Carveda tablet by Ferozesons The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Carvedilol6.25mg el claim: evision of formulation from film coated tablet to uncoated tablet as &A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, FBX 80mg Tablet

		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-gout Preparations
		Form 5
	Type of Form	
	Finished Product Specification Pack size & Demanded Price	Firm has claimed in-house specifications
		As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Zurig Tablet by Getz
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator ³ .	
	 Decision: Approved with Innovator's s Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. 	or revision of specifications as per notification No.F.7-11/2012-
180.	Name and address of manufacturer /	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II,
100.	Applicant	Industrial Estate Hattar,
	Brand Name +Dosage Form + Strength	Olme 20mg Tablet
	Composition	Each Film Coated Tablet Contains:
	Composition	Olmesartan Medoxomil20mg
	Diary No. Date of R& I & fee	Dy No. 16158: 07-03-2019
	Biary No. Date of R& 1& ICC	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Olmie Tablet by Getz
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-
		DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
181.	Name and address of manufacturer /	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II,
	Applicant	Industrial Estate Hattar,
	Brand Name +Dosage Form + Strength	Olme 40mg Tablet
	Composition	Each Film Coated Tablet Contains:
	D: N D (CD 0 1 0 C	Olmesartan Medoxomil40mg
	Diary No. Date of R& I & fee	Dy No. 16164: 07-03-2019
	Dhamma a la si a l Craum	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Olmie Tablet by Getz
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator ³ .	
40-	Decision: Approved.	
182.	Name and address of manufacturer /	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II,
	Applicant Brand Name +Dosage Form + Strength	Industrial Estate Hattar, Olme Plus 40/5mg Tablet
		Each Film Coated Tablet Contains:
	Composition	Olmesartan Medoxomil40mg
		Amlodipine Besylate Eq To Amlodipine5mg
	Diary No. Date of R& I & fee	Dy No. 16159: 07-03-2019
	Diary 110. Date of No. 1 & 166	PKR 20,000/-: 06-03-2019
1	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel
Ì		, , , , , , , , , , , , , , , , , , ,
		blockers
	Type of Form	blockers Form 5

	Einighad Dundwat Congification	USP
	Finished Product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved.
	Regulatory Authorities.	
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-
		DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
183.	Name and address of manufacturer /	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II,
	Applicant	Industrial Estate Hattar,
	Brand Name +Dosage Form + Strength	Olme Plus 20/10mg Tablet
	Composition	Each Film Coated Tablet Contains:
	•	Olmesartan Medoxomil20mg
		Amlodipine Besylate Eq To Amlodipine10mg
	Diary No. Date of R& I & fee	Dy No. 16157: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel
	Thurmue or ogress or out	blockers
	Town of Forms	Form 5
	Type of Form	
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved.
	Regulatory Authorities.	
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-
	_	DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator ³ .	
	Decision: Approved.	
184.	Name and address of manufacturer /	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II,
	Applicant	Industrial Estate Hattar,
	Brand Name +Dosage Form + Strength	Olme Plus 40/10mg Tablet
		Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains:
	Brand Name +Dosage Form + Strength	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg
	Brand Name +Dosage Form + Strength Composition	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg
	Brand Name +Dosage Form + Strength	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019
	Brand Name +Dosage Form + Strength Composition	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved.
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson The firm has submitted copy of GMP Certificate No. F.11-76/2022-
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson The firm has submitted copy of GMP Certificate No. F.11-76/2022-
185.	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved.	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
185.	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer /	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II,
185.	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,
185.	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Helirab 20mg Tablet
185.	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Helirab 20mg Tablet Each Enteric Coated Tablet Contains:
185.	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Helirab 20mg Tablet Each Enteric Coated Tablet Contains: Rabeprazole Sodium20mg
185.	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Helirab 20mg Tablet Each Enteric Coated Tablet Contains: Rabeprazole Sodium20mg Dy No. 16658: 07-03-2019
185.	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Helirab 20mg Tablet Each Enteric Coated Tablet Contains: Rabeprazole Sodium20mg Dy No. 16658: 07-03-2019 PKR 20,000/-: 06-03-2019
185.	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Helirab 20mg Tablet Each Enteric Coated Tablet Contains: Rabeprazole Sodium20mg Dy No. 16658: 07-03-2019 PKR 20,000/-: 06-03-2019 Proton Pump Inhibitors
185.	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Helirab 20mg Tablet Each Enteric Coated Tablet Contains: Rabeprazole Sodium20mg Dy No. 16658: 07-03-2019 PKR 20,000/-: 06-03-2019 Proton Pump Inhibitors Form 5
185.	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Olme Plus 40/10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil40mg Amlodipine Besylate Eq To Amlodipine10mg Dy No. 16160: 07-03-2019 PKR 20,000/-: 06-03-2019 Angiotensin II receptor blockers (ARBs) and calcium channel blockers Form 5 USP As per SRO USFDA Approved. Baritec-A Tablets by Barrett Hodgson The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Helirab 20mg Tablet Each Enteric Coated Tablet Contains: Rabeprazole Sodium20mg Dy No. 16658: 07-03-2019 PKR 20,000/-: 06-03-2019 Proton Pump Inhibitors

	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	The state of the s
	Me-too status	Protorib Tablet by Helix
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-
	GMI status	DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator ³ .	Ditti () issued on 10,00,2022 yand thi co,00,2022.
	Decision: Approved with Innovator's s	necifications
		or revision of specifications as per notification No.F.7-11/2012-
	B&A/DRAP dated 07-05-2021	
186.	Name and address of manufacturer /	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II,
100.	Applicant	Industrial Estate Hattar,
	Brand Name +Dosage Form + Strength	Riswrd 3mg Tablet
	Composition	Each Film Coated Tablet Contains:
	Composition	Risperidone3mg
	Diary No. Date of R& I & fee	Dy No. 16172: 07-03-2019
	Blary 140. Bate of Rec 1 & 1ce	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	WHKA Approved
	Me-too status	Neo-Risp Tablet by Wilshire
	GMP status	The firm has submitted copy of GMP Certificate No. F.11-76/2022-
	GWF status	DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
	Remarks of the Evaluator ³ .	Revise your label claim along with submission of 7500 fee as per the
	Remarks of the Evaluator.	innovator's product as per following:
		Each Tablet Contains:
		Risperidone3mg
	Decision: Approved with following lab	
	Each Tablet Contains:	ci Cidilli.
	Risperidone3mg Firm shall submit 7 500/- fee for r	evision of formulation from film coated tablet to uncoated tablet as
	• Firm shall submit 7,500/- fee for r	evision of formulation from film coated tablet to uncoated tablet as &A/DRAP dated 07-05-2021.
187.	• Firm shall submit 7,500/- fee for r per notification No.F.7-11/2012-B.	&A/DRAP dated 07-05-2021.
187.	• Firm shall submit 7,500/- fee for r per notification No.F.7-11/2012-B Name and address of manufacturer /	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II,
187.	Firm shall submit 7,500/- fee for r per notification No.F.7-11/2012-B Name and address of manufacturer / Applicant	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,
187.	 Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength 	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet
187.	Firm shall submit 7,500/- fee for r per notification No.F.7-11/2012-B Name and address of manufacturer / Applicant	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains:
187.	Firm shall submit 7,500/- fee for r per notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg
187.	 Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength 	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire The firm has submitted copy of GMP Certificate No. F.11-76/2022-
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022.
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following:
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone 4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains:
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Risperidone4mg
187.	Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labely and submit	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Risperidone4mg
187.	• Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laborator and the state of the state of the state of the Evaluator.	&A/DRAP dated 07-05-2021. M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Risperidone4mg
187.	• Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laborator and the state of the Euch Tablet Contains: Risperidone4mg	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Risperidone4mg
187.	• Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following labe Each Tablet Contains: Risperidone4mg • Firm shall submit 7,500/- fee for respective states and submit 7,50	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Risperidone4mg el claim:
187.	• Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laborator and the state of the Euch Tablet Contains: Risperidone4mg	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Risperidone4mg el claim: evision of formulation from film coated tablet to uncoated tablet as &A/DRAP dated 07-05-2021.
	• Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laberator Each Tablet Contains: Risperidone4mg • Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer /	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Risperidone4mg el claim: evision of formulation from film coated tablet to uncoated tablet as &A/DRAP dated 07-05-2021. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B,
	• Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with following laberator Each Tablet Contains: Risperidone4mg • Firm shall submit 7,500/- fee for reper notification No.F.7-11/2012-B.	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, Riswrd 4mg Tablet Each Film Coated Tablet Contains: Risperidone4mg Dy No. 16173: 07-03-2019 PKR 20,000/-: 06-03-2019 Other antipsychotics Form 5 USP As per SRO MHRA Approved Neo-Risp Tablet by Wilshire The firm has submitted copy of GMP Certificate No. F.11-76/2022-DRAP-69 issued on 10/06/2022 valid till 30/03/2022. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Risperidone4mg el claim: evision of formulation from film coated tablet to uncoated tablet as &A/DRAP dated 07-05-2021.

	Composition	Each Film Coated Tablet Contains:
		Mecobalamin500mcg
	Diary No. Date of R& I & fee	Dy No. 16668: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Vitamin B12 analogue
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification but available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	PMDA Japan Approved
	Regulatory Authorities.	
	Me-too status	Methycobal tablet by Hilton
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
		innovator's product as per following:
		Each Sugar Coated Tablet Contains:
		Mecobalamin500mcg
	Decision: Approved with JP specification	
	Each Sugar Coated Tablet Co	ntains:
	Mecobalamin500mcg	
		vision of formulation from film coated tablet to sugar coated tablet as
	per notification No.F.7-11/2012-B&	
189.	Name and address of manufacturer /	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B,
	Applicant	Phase I-II, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	A-Zint 6/25 mg Capsule
	Composition	Each Capsule Contains:
		Olanzapine6mg
	D' N. D CD 0 I 0 C	Fluoxetine25mg
	Diary No. Date of R& I & fee	Dy No. 16680: 07-03-2019
	Pharmacological Group	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Atypical antipsychotic and a selective serotonin
	T C.F	reuptake inhibitor Form 5
	Type of Form	USP
	Finished Product Specification Pack size & Demanded Price	
	Approval status of product in Reference	As per SRO USFDA Approved
	Regulatory Authorities.	OSIDA Approved
	Me-too status	Byflanz capsule by martin dow
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of
	GMI status	inspection dated 12-10-2022
	Remarks of the Evaluator ³ .	Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each Capsule Contains:
		Olanzapine (as HCl)6mg
		Fluoxetine25mg
	Decision: Approved with following labor	el claim:
	Each Capsule Contains:	
	Olanzapine (as HCl)6m	ng
	Fluoxetine25mg	
		s. 30,000/- for correction/pre-approval change in product label claim
	as per notification No.F.7-11/2 letter.	012-B&A/DRAP dated 07-05-2021, before issuance of registration
190.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	D-Tam Plus 20/5 mg Tablet
	Composition	Each Film Coated Tablet Contains:
	^	Amlodipine Besylate Eq. To Amlodipine5mg
		Olmesartan Medoxomil20mg
	Diary No. Date of R& I & fee	Dy No. 17372: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel
		blockers
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	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved.
	Regulatory Authorities.	CSI BITTIPPIO (Cd.
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of
	GIVIP status	inspection dated 12-10-2022
	Remarks of the Evaluator ³ .	•
		•
101	Decision: Approved.	MINIST DELLE STREET
191.	Name and address of manufacturer /	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B,
	Applicant	Phase I-II, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Pixel CR 12.5mg Tablet
	Composition	Each Film Coated Controlled Release Tablet Contains:
	D: N D : CD 0 1 0 C	Paroxetine As Hcl Hemihydrate12.5mg
	Diary No. Date of R& I & fee	Dy No. 16679: 07-03-2019
	7	PKR 20,000/-: 07-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Seroxat CR Tablet by GSK
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of
		inspection dated 12-10-2022
	Remarks of the Evaluator ³ .	Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each enteric, film coated, controlled release tablet contains:
		Paroxetine (as HCl)12.5mg
	Decision: Approved with following labor	el claim:
	Each enteric, film coated	, controlled release tablet contains:
	Paroxetine (as HCl)12.	5
	()	Smg
	` ,	omg 80,000/- for correction/pre-approval change in product label claim as
	• The firm shall submit fee of Rs. 3	
192.	• The firm shall submit fee of Rs. 3	30,000/- for correction/pre-approval change in product label claim as
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer /	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B,
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains:
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved Myolax tablet by Genetics
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	38.A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved Myolax tablet by Genetics Firm has submitted copy of GMP certificate issued on the basis of
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	80,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved Myolax tablet by Genetics Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	38.A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved Myolax tablet by Genetics Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022 • Revise your label claim along with submission of 7500 fee as per the
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	38.A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved Myolax tablet by Genetics Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022 • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following:
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	38.A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved Myolax tablet by Genetics Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022 • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains:
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	38.A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved Myolax tablet by Genetics Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022 • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Thiocolchicoside4mg
192.	The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with Innovator's s	38.A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved Myolax tablet by Genetics Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022 • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains:
192.	• The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with Innovator's s Each Tablet Contains:	38.A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved Myolax tablet by Genetics Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022 • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Thiocolchicoside4mg
192.	• The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with Innovator's s Each Tablet Contains: Thiocolchicoside4mg	30,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved Myolax tablet by Genetics Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022 • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Thiocolchicoside4mg pecifications and with following label claim:
192.	• The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with Innovator's s Each Tablet Contains: Thiocolchicoside4mg • Firm shall submit 7,500/- fee for r	30,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved Myolax tablet by Genetics Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022 • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Thiocolchicoside4mg pecifications and with following label claim:
192.	• The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with Innovator's s Each Tablet Contains: Thiocolchicoside4mg	30,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved Myolax tablet by Genetics Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022 • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Thiocolchicoside4mg pecifications and with following label claim: evision of formulation from film coated tablet to uncoated tablet as &A/DRAP dated 07-05-2021.
	• The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with Innovator's s Each Tablet Contains: Thiocolchicoside4mg • Firm shall submit 7,500/- fee for r per notification No.F.7-11/2012-B.	30,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan C-Tol 4mg Tablet Each Film Coated Tablet Contains: Thiocolchicoside4mg Dy No. 16681: 07-03-2019 PKR 20,000/-: 06-03-2019 Muscle Relaxants, Centrally Acting Agents Form 5 Firm has claimed in-house specifications As per SRO ANSM France Approved Myolax tablet by Genetics Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022 • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Thiocolchicoside4mg pecifications and with following label claim:

	Brand Name +Dosage Form + Strength	Winterm Injection 80mg/ml
	Composition	Each ml Contains:
	Composition	Artemether80mg
	Diary No. Date of R& I & fee	Dy No. 14827: 07-03-2019
		PKR 20,000/-: 28-02-2019
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	Ph. Int.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Could not be confirmed in any RRA
	Regulatory Authorities.	However its monograph is available in Ph. Int and is also available in NEML
	Me-too status	Artisrch Injection by Medisearch
	GMP status	The last inspection conducted on 31-01-2022 and report
	Remarks of the Evaluator ³ .	concludes that overall GMP compliance was found good.
	Remarks of the Evaluators.	• Firm has liquid injectable (general) section.
		• WHO essential medicine list 2022 specifies Artemether IV: 80 mg per mL in 1 mL ampoule (oily injection) under the section
		Antimalarial medicines > For curative treatment.
		ed the matter regarding availability of applied formulation in refrence
		dering the recommendation of applied formulation in WHO essential
10.1	medicine list, decided to approved the a	
194.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Wincip 125mg/5ml Granules
	Composition	Each 5ml Granules Suspension Contains:
	1	Ciprofloxacin HCl125mg
	Diary No. Date of R& I & fee	Dy No. 14651: 07-03-2019
		PKR 20,000/-: 04-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Registration Board in 269 th meeting approved the formulation of
	Regulatory Authorities.	ciprofloxacin 125mg/5ml granules and solvent for oral suspension
	Me-too status	Novidat suspension by Sami
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each 5ml of reconstituted suspension contains:
		Ciprofloxacin125mg
	Decision: Defferred the case. The regi	stration Board discussed and deliberated the case in detail regarding
		an expert working group consisting of members from RB, DRAP,
		ssionls in the relevant fields, stake holders and member nominated by
		to the matter considering all the technical aspects and will forward its
10.	report to RB for its consideration and o	
195.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength Composition	Citolin Injection IM/IV
	Composition	Each 4ml Ampoule Contains: Citicoline as Sodium250mg
	Diary No. Date of R& I & fee	Dy No. 14649: 07-03-2019
	Diary No. Date of Ree Lee Ice	PKR 20,000/-: 04-03-2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	4ml ampoule: As per SRO
	Approval status of product in Reference	Somazine 1000 mg, solution for injection: Each 4 ml ampoule contains
	Regulatory Authorities.	1000 mg citicoline (as sodium salt).
		Spain Approved
	Me-too status	Injcho 250mg/ml Injection (4ml) of Ameer & Adnan Pharma

	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	D 1 C. 4 E 1 3	
	Remarks of the Evaluator ³ .	• Firm has liquid injectable (general) section.
		Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each 4ml Ampoule Contains:
		Citicoline as Sodium1000mg
	Decision: Approved with Innovator's s	pecifications and with following label claim:
	Each 4ml Ampoule Conta	
	Citicoline as Sodium10	
		s. 30,000/- for correction/pre-approval change in product label claim
	_	012-B&A/DRAP dated 07-05-2021, before issuance of registration
	letter.	T
196.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Citolin Injection IM/IV
	Composition	Each 4ml Ampoule Contains:
	_	Citicoline As Sodium500mg
	Diary No. Date of R& I & fee	Dy No. 14648: 07-03-2019
		PKR 20,000/-: 04-03-2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	4ml ampoule: As per SRO
	Approval status of product in Reference	CITICOLINA KERN PHARMA 500 mg solution for injection EFG is
	Regulatory Authorities.	presented in transparent glass ampoules. Each 4 ml ampoule contains
		500 mg CITICOLINE (as sodium salt).
		Spain Approved
	Me-too status	Seeto-las Injection 500mg/4ml of Astellas Pharma
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	Firm has liquid injectable (general) section.
	Decision: Approved with Innovator's s	
197.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Deslo 5mg Tablet
	Composition	Each Tablet Contains:
	-	Each Tablet Contains: Desloratadine5mg
	Composition Diary No. Date of R& I & fee	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019
	Diary No. Date of R& I & fee	Each Tablet Contains: Desloratadine5mg
	-	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019
	Diary No. Date of R& I & fee Pharmacological Group	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019
	Diary No. Date of R& I & fee Pharmacological Group Type of Form	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use
	Diary No. Date of R& I & fee Pharmacological Group	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP
	Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO
	Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP
	Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved
	Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton
	Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report
	Diary No. Date of R& I & 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	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of 7500 fee as per the
	Diary No. Date of R& I & 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	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following:
	Diary No. Date of R& I & 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	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains:
	Diary No. Date of R& I & 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 ³ .	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Desloratadine5mg
	Diary No. Date of R& I & 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 ³ . Decision: Approved with following labeling the product of the state of the	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Desloratadine5mg el claim:
	Diary No. Date of R& I & 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 ³ . Decision: Approved with following laberach Film Coated Tablet Control	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Desloratadine5mg el claim:
	Diary No. Date of R& I & 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 ³ . Decision: Approved with following laber Each Film Coated Tablet Compessorated in Each Smg	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Desloratadine5mg el claim: tains:
	Diary No. Date of R& I & 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 ³ . Decision: Approved with following labe Each Film Coated Tablet Com Desloratadine5mg • Firm shall submit 7,500/- fee for	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Desloratadine5mg el claim: tains: revision of formulation from uncoated tablet to film coated tablet as
198	Diary No. Date of R& I & 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 ³ . Decision: Approved with following lab Each Film Coated Tablet Com Desloratadine5mg Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-1	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Desloratadine5mg el claim: tains: revision of formulation from uncoated tablet to film coated tablet as 3&A/DRAP dated 07-05-2021.
198.	Diary No. Date of R& I & 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 ³ . Decision: Approved with following labe Each Film Coated Tablet Compessoratedine5mg Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer /	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Desloratadine5mg el claim: tains: revision of formulation from uncoated tablet to film coated tablet as 3&A/DRAP dated 07-05-2021. M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
198.	Diary No. Date of R& I & 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 ³ . Decision: Approved with following labe Each Film Coated Tablet Compesioratadine5mg Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer / Applicant	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Desloratadine5mg el claim: tains: revision of formulation from uncoated tablet to film coated tablet as 3&A/DRAP dated 07-05-2021. M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan
198.	Diary No. Date of R& I & 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 ³ . Decision: Approved with following labe Each Film Coated Tablet Compessoratedine5mg Firm shall submit 7,500/- fee for per notification No.F.7-11/2012-I Name and address of manufacturer /	Each Tablet Contains: Desloratadine5mg Dy No. 14794: 07-03-2019 PKR 20,000/-: 28-02-2019 Other antihistamines for systemic use Form 5 USP As per SRO USFDA Approved Destina Tablet by Hilton The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Desloratadine5mg el claim: tains: revision of formulation from uncoated tablet to film coated tablet as 3&A/DRAP dated 07-05-2021. M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super

		Diclofenac Sodium75mg
	Diam No Data of D 0 I 0 for	
	Diary No. Date of R& I & fee	Dy No. 14652: 07-03-2019
		PKR 20,000/-: 28-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	ANSM France Approved
	Regulatory Authorities.	
	Me-too status	Dicloran Injection by Sami
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	Firm has liquid injectable (general) section.
	Decision: Approved with Innovator's s	
		or revision of specifications as per notification No.F.7-11/2012-
100	B&A/DRAP dated 07-05-2021. Name and address of manufacturer /	
199.		M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Windic L Injection 2ml
	Composition	Each 2ml ampoule Contains:
		Diclofenac Sodium75mg
		Lignocaine HC120mg
	Diary No. Date of R& I & fee	Dy No. 14803: 07-03-2019
		PKR 20,000/-: 04-03-2019
	Pharmacological Group	NSAID with local Anaesthetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Diclofenac-Mepha 75 ampoules IM
	Regulatory Authorities.	1 ampoule of 2 ml contains: 75 mg diclofenac sodium,
	regulatory realistics.	20 mg Lidocaine hydrochloride (Swiss medics
		approved)
	Me too status	approved).
	Me-too status	Lisodim IM Injection by Surge
	Me-too status GMP status	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report
	GMP status	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	GMP status Remarks of the Evaluator ³ .	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section.
	GMP status Remarks of the Evaluator ³ . Decision: Approved with Innovator's s	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications.
	GMP status Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section.
	GMP status Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021.	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012-
200.	GMP status Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer /	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
200.	GMP status Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan
200.	GMP status Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml
200.	GMP status Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains:
200.	GMP status Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HC140mg
200.	GMP status Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains:
200.	GMP status Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HC140mg
200.	GMP status Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HCl40mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HC140mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HCl40mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic Form 5
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HC140mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic Form 5 Firm has claimed in-house specifications
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HC140mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic Form 5 Firm has claimed in-house specifications As per SRO
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HC140mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic Form 5 Firm has claimed in-house specifications As per SRO 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HC140mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic Form 5 Firm has claimed in-house specifications As per SRO 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved)
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HC140mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic Form 5 Firm has claimed in-house specifications As per SRO 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HCl40mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic Form 5 Firm has claimed in-house specifications As per SRO 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved)
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HCl40mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic Form 5 Firm has claimed in-house specifications As per SRO 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved) 3. No-Spa 20 mg/ml solution for injection by Chinoin Pharmaceutical
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s • Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HCl40mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic Form 5 Firm has claimed in-house specifications As per SRO 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved) 3. No-Spa 20 mg/ml solution for injection by Chinoin Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HCl40mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic Form 5 Firm has claimed in-house specifications As per SRO 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved) 3. No-Spa 20 mg/ml solution for injection by Chinoin Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal Products, Bulgaria Approved)
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HCl40mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic Form 5 Firm has claimed in-house specifications As per SRO 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved) 3. No-Spa 20 mg/ml solution for injection by Chinoin Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal Products, Bulgaria Approved) Dytra Injection by Tabros
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HCl40mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic Form 5 Firm has claimed in-house specifications As per SRO 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) 2. NO-SPA 40 mg / 2 ml solution for injection by Chinoin Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal Products, Bulgaria Approved) Dytra Injection by Tabros The last inspection conducted on 31-01-2022 and report
200.	Remarks of the Evaluator ³ . Decision: Approved with Innovator's s Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Lisodim IM Injection by Surge The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Firm has liquid injectable (general) section. pecifications. revision of specifications as per notification No.F.7-11/2012- M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Drotawin Injection 40mg/2ml Each 2ml Contains: Drotaverine As HCl40mg Dy No. 14645: 07-03-2019 PKR 20,000/-: 04-03-2019 Anti-spasmodic Form 5 Firm has claimed in-house specifications As per SRO 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved) 3. No-Spa 20 mg/ml solution for injection by Chinoin Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal Products, Bulgaria Approved) Dytra Injection by Tabros

	• Revise your label claim along with submission of full fee as per the
	innovator's product as per following:
	Each 2ml ampoule Contains:
	Drotaverine HCl40mg

Decision: Registration Board deliberated the matter in detail and observed that the applied formulation is approved by three European Union countries i.e., Hungary, Romania & Bulgaria wherein Hungary & Romania are also PIC/S Member countries and the applied formulation is also already approved by DRAP, The Board therefore decided to approved the product with with Innovator's specifications and with following label claim:

Each 2ml ampoule Contains:

Drotaverine HCl...40mg

The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

201.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Zippo Capsule 20mg
	Composition	Each Enteric Coated Pellets Contains:
	_	Duloxetine As Hcl20mg
	Diary No. Date of R& I & fee	Dy No. 14791: 07-03-2019
	•	PKR 20,000/-: 04-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Dulan Capsule by Hilton
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	• Provide source of pellets along with COA, stability study data of 3
		batches of pellets, GMP certificate of pellets manufacturer and
		differential fee (in case of imported pellets).
		• Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each Capsule Contains:
		Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine20mg

Decision: Approved with following label claim:

Each Capsule Contains:

Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine...20mg

- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.
- Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.

202.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Zippo Capsule 30mg
	Composition	Each Enteric Coated Pellets Contains:
		Duloxetine As Hcl30mg
	Diary No. Date of R& I & fee	Dy No. 14792: 07-03-2019
		PKR 20,000/-: 04-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Dulan Capsule by Hilton
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.

	• The firm shall submit fee of Rs. 3 per notification No.F.7-11/2012-I	 Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine30mg Coated Pellets Eq. To Duloxetine30mg 60,000/- for correction/pre-approval change in product label claim as 3&A/DRAP dated 07-05-2021, before issuance of registration letter. ts along with COA, stability study data of 3 batches of pellets, GMP 	
		er and differential fee (in case of imported pellets) before issuance of	
	registration letter.		
203.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super	
	Applicant	Highway, Phase-II, Karachi, Pakistan	
	Brand Name +Dosage Form + Strength	Drowznel Syrup 5mg/5ml	
	Composition	Each 5ml Contains:	
		Ebastine5mg	
	Diary No. Date of R& I & fee	Dy No. 14793: 07-03-2019	
		PKR 20,000/-: 04-03-2019	
	Pharmacological Group	Other antihistamines for systemic use	
	Type of Form	Form 5	
	Finished Product Specification	Firm has claimed in house specifications	
	Pack size & Demanded Price	As per SRO	
	Approval status of product in Reference Regulatory Authorities.	Ebastel 1 mg/ml oral solution Spain Approved	
	Me-too status	Kestine oral liquid by Highnoon	
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.	
	Remarks of the Evaluator ³ .	•	
	Decision: Approved with Innovator's s		
	B&A/DRAP dated 07-05-2021	• 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.	
204.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan	
	Brand Name +Dosage Form + Strength	Fluzip Tablet 120mg	
	Composition	Each Film Coated Tablet Contains:	
	*	Fexofenadine HCl120mg	
	Diary No. Date of R& I & fee	Dy No. 14807: 07-03-2019	
		PKR 20,000/-: 28-02-2019	
	Pharmacological Group	Antihistamines For Systemic Use	
	Type of Form	Form 5	
	Finished Product Specification	USP	
	Pack size & Demanded Price	As per SRO	
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved	
	Me-too status	Fexet Tablets by Getz	
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.	
	Remarks of the Evaluator ³ .	•	
	Decision: Approved.		
205.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super	
	Applicant	Highway, Phase-II, Karachi, Pakistan	
	Brand Name +Dosage Form + Strength	G Win 320mg Tablet	
	Composition	Feeh Film Coated Tablet Contains:	

Each Film Coated Tablet Contains:

Gemifloxacin Mesylate...320mg

Dy No. 14805: 07-03-2019 PKR 20,000/-: 04-03-2019

Fluoroquinolones

Form 5

Composition

Type of Form

Diary No. Date of R& I & fee

Pharmacological Group

Finished Product Specification	Firm has claimed in-house specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	Discontinued in FDA / applicant withdraw its application for Marketing
Regulatory Authorities.	authorization in EMA
Me-too status	Gemixa tablet by Bosch Pharma
GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
Remarks of the Evaluator ³ .	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	• Revise your label claim along with submission of full fee as per the innovator's product as per following:
	Each Film Coated Tablet Contains:
	Gemifloxacin (as mesylate)320mg

Decision: Registration Board was apprised that the applied formulation is discontinued in USFDA and the marketing authorization application in EMA has been withdrawn due to negative risk benefit ratio. Based upon the findings of the EMA, the Board decided as under:

- Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
- Directed PE&R Division to present the detailed case in forthcoming meeting of Registration Board along with details of already registered products of same formulation.

206.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Valturn D 80mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains:
	-	Hydrochlorothiazide80mg
		Valsartan12.5mg
	Diary No. Date of R& I & fee	Dy No. 14779: 07-03-2019
	•	PKR 20,000/-: 28-02-2019
	Pharmacological Group	Thiazides, combinations with other drugs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	N IDELLI N
	Me-too status	Nuval-D Tablet by Pharmevo
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	•
	Decision: Approved.	
207.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Valturn D Tablet 160/25mg
	Composition	Each Film Coated Tablet Contains:
		Hydrochlorothiazide160mg
		Valsartan25mg
	Diary No. Date of R& I & fee	Dy No. 14780: 07-03-2019
		PKR 20,000/-: 28-02-2019
	Pharmacological Group	Thiazides, combinations with other drugs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Nuval-D Tablet by Pharmevo
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	•
	Decision: Approved.	
208.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Monofer 500mg/5ml Injection

Composition	Each 5ml Contains:
	One Milimeter for Solution Contains 100mg Iron Isomaltoside
	1000:500mg/5ml
Diary No. Date of R& I & fee	Dy No. 14656: 07-03-2019
	PKR 20,000/-: 04-03-2019
Pharmacological Group	Iron parenteral preparation
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	5ml ampoule: As per SRO
Approval status of product in Reference	TGA approved
Regulatory Authorities.	
Me-too status	Maltoside 500mg/5ml Injection of Nabiqasim
GMP status	The last inspection conducted on 31-01-2022 and report
	concludes that overall GMP compliance was found good.
Remarks of the Evaluator ³ .	Firm has liquid injectable (general) section.
	• Revise your label claim along with submission of full fee as per the
	innovator's product as per following:
	Each 5ml ampoule contains:
	Iron isomaltoside 1000 (ferric derisomaltose) eq to elemental iron
	500mg
Decision: Approved with following lab	el claim:

Each 5ml ampoule contains:

Iron isomaltoside 1000 (ferric derisomaltose) eq to elemental iron ...500mg

• The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

209.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	W Malt 100mg Tablet
	Composition	Each Tablet Contains:
		Iron (iii) Hydroxide Polymaltose Equivalent To Elemental
		Iron100mg
	Diary No. Date of R& I & fee	Dy No. 14806: 07-03-2019
		PKR 20,000/-: 04-03-2019
	Pharmacological Group	Hematinic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	TGA approved
	Regulatory Authorities.	
	Me-too status	Tyzofer Tablet by Jinnah Pharma
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
		innovator's product as per following:
		Each film coated tablet contains:
		Iron (III) Hydroxide Polymaltose Complex eq to Elemental
		Iron100mg

Approved with Innovator's specifications and with following label claim:

Each film coated tablet contains:

Iron (III) Hydroxide Polymaltose Complex eq to Elemental Iron...100mg

210.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Lakasawin Infusion 200mg/20ml
	Composition	Each ml Contains:
		Lacosamide10mg
	Diary No. Date of R& I & fee	Dy No. 14646: 07-03-2019
		PKR 20,000/-: 28-02-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5

	Einighed Duedwet Charification	BP
	Finished Product Specification Pack size & Demanded Price	
		20ml glass vial: As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	Y 1 Y 1 1 YY
	Me-too status	Lacolep Injection by Hilton
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	• Firm has liquid injectable (general) section.
	Decision: Approved.	
211.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Wincetam Injection 500mg/5ml
	Composition	Each 5ml ampoule contains:
	D' N D CD0 I 0 C	Levetiracetam500mg
	Diary No. Date of R& I & fee	Dy No. 14786: 07-03-2019
	D	PKR 20,000/-: 28-02-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Levetiracetam 100 mg / mL Concentrate for solution for infusion
	Regulatory Authorities.	(MHRA Approved)
	Me-too status	Lumark Injection by Searle
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	• Firm has liquid injectable (general) section.
	Decision: Approved with Innovator's s	<u>-</u>
		or revision of specifications as per notification No.F.7-11/2012-
212	B&A/DRAP dated 07-05-2021	
212.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength Composition	Levoride 25mg Tablet Each Film Coated Tablet Contains:
	Composition	Levosulpiride25mg
	Diary No. Date of R& I & fee	Dy No. 14797: 07-03-2019
	Dialy No. Date of R& 1 & Ice	PKR 20,000/-: 28-02-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	AIFA Italy approved.
	Regulatory Authorities.	All'A Italy approved.
	Me-too status	Levide tablet by Swiss Pharma
	GMP status	The last inspection conducted on 31-01-2022 and report
	GMI status	concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	Revise your label claim along with submission of 7500 fee as per the
	Remarks of the Evaluator.	innovator's product as per following:
		Each Tablet Contains:
		Levosulpiride25mg
	Decision: Approved with Innovator's s	pecifications and with following label claim:
	Each Tablet Contains:	r · · · · · · · · · · · · · · · · · · ·
	Levosulpiride25mg	
		evision of formulation from film coated tablet to uncoated tablet as
	per notification No.F.7-11/2012-B	
213.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Levoride Tablet 50mg
	Composition	Each Film Coated Tablet Contains:
		Levosulpiride50mg
	Diary No. Date of R& I & fee	Dy No. 14798: 07-03-2019
		PKR 20,000/-: 04-03-2019
	Pharmacological Group	Antipsychotic

	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	AIFA Italy approved.
	Regulatory Authorities.	AIFA italy approved.
		I saids tablet has Carine Dhamas
	Me-too status	Levide tablet by Swiss Pharma
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
		innovator's product as per following:
		Each Tablet Contains:
		Levosulpiride50mg
		pecifications and with following label claim:
	Each Tablet Contains:	
	Levosulpiride50mg	
		evision of formulation from film coated tablet to uncoated tablet as
	per notification No.F.7-11/2012-B	
214.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Lidowin Injection 20mg/2ml
	Composition	Each 2ml ampoule contains:
		Lignocaine HCl20mg
	Diary No. Date of R& I & fee	Dy No. 14644: 07-03-2019
		PKR 20,000/-: 28-02-2019
	Pharmacological Group	Local anesthetics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Lycas Injection by Pharmedic Laboratories
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	Firm has liquid injectable (general) section.
	Decision: Approved.	
215.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Linxo Tablet 600mg
	Composition	Each Film Coated Tablet Contains:
		Linezolid600mg
	Diary No. Date of R& I & fee	Dy No. 14790: 07-03-2019
		PKR 20,000/-: 28-02-2019
	Pharmacological Group	Other antibacterials
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Nezkil Tablet by S.J&G Fazul Ellahie
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	•
	Decision: Approved with Innovator's s	necifications.
		or revision of specifications as per notification No.F.7-11/2012-
216.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
210.	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Meconium 500mcg
	Composition	Each Sugar Coated Tablet Contains:
	Composition	Mecobalamin500mcg
	Diary No. Date of R& I & fee	Dy No. 14640: 07-03-2019
	Dimy 110. Dute of No. 1 of Ice	PKR 20,000/-: 04-03-2019
1		1 1XX 20,000/ UT-03-201/

	Pharmacological Group	Vitamin B12 analogue
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification but available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	PMDA Japan Approved
	Regulatory Authorities.	This it supun rippio vod
	Me-too status	Methycobal tablet by Hilton
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	•
	Decision: Approved with JP specification	ons.
	 Firm shall submit 7,500/- fee for B&A/DRAP dated 07-05-2021. 	or revision of specifications as per notification No.F.7-11/2012-
217.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Nimso 100mg Tablet
	Composition	Each Film Coated Tablet Contains:
	1	Nimsulide100mg
	Diary No. Date of R& I & fee	Dy No. 14796: 07-03-2019
		PKR 20,000/-: 28-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	HPRA Ireland Approved
	Regulatory Authorities.	
	Me-too status	Nise Tablet by Pharmevo
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	•
	Decision: Approved.	
210		M/ W' 41 T 1 4 ' D 4 T 4 1 T A10/4 CITED C
218.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
218.	Name and address of manufacturer / Applicant	Highway, Phase-II, Karachi, Pakistan
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution
218.	Name and address of manufacturer / Applicant	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains:
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved.
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved. Nootropil Syrup by AGP
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved. Nootropil Syrup by AGP The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of full fee as per the
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved. Nootropil Syrup by AGP The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of full fee as per the innovator's product as per following:
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved. Nootropil Syrup by AGP The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains:
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved. Nootropil Syrup by AGP The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains: Piracetam1gm
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved. Nootropil Syrup by AGP The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains:
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with Innovator's s Each 5ml Contains:	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved. Nootropil Syrup by AGP The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains: Piracetam1gm
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with Innovator's s Each 5ml Contains: Piracetam1gm	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved. Nootropil Syrup by AGP The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains: Piracetam1gm pecifications and with following label claim:
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with Innovator's syracetam1gm The firm shall submit fee of Rs. 30	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved. Nootropil Syrup by AGP The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains: Piracetam1gm pecifications and with following label claim:
218.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with Innovator's syracetam1gm The firm shall submit fee of Rs. 30	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved. Nootropil Syrup by AGP The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains: Piracetam1gm pecifications and with following label claim:
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with Innovator's s Each 5ml Contains: Piracetam1gm The firm shall submit fee of Rs. 30 per notification No.F.7-11/2012-Ba	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved. Nootropil Syrup by AGP The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains: Piracetam1gm pecifications and with following label claim:
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with Innovator's s Each 5ml Contains: Piracetam1gm The firm shall submit fee of Rs. 30 per notification No.F.7-11/2012-Bo Name and address of manufacturer /	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved. Nootropil Syrup by AGP The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains: Piracetam1gm pecifications and with following label claim: 0,000/- for correction/pre-approval change in product label claim as &A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan Rabi Win 20mg Tablet
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved with Innovator's s Each 5ml Contains: Piracetam1gm The firm shall submit fee of Rs. 30 per notification No.F.7-11/2012-Bo Name and address of manufacturer / Applicant	Highway, Phase-II, Karachi, Pakistan Cetram 200mg/ml Oral Solution Each 5ml Contains: Piracetam200mg Dy No. 14808: 07-03-2019 PKR 20,000/-: 04-03-2019 Other psychostimulants and nootropics Form 5 Firm has claimed in-house specifications As per SRO NOOTROPYL 20%, oral solution (Piracetam 200mg/ml) ANSM France Approved. Nootropil Syrup by AGP The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains: Piracetam1gm pecifications and with following label claim: 0,000/- for correction/pre-approval change in product label claim as &A/DRAP dated 07-05-2021, before issuance of registration letter. M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan

	Diary No. Date of R& I & fee	Dy No. 14809: 07-03-2019
	Pharmacological Group	PKR 20,000/-: 04-03-2019 Proton Pump Inhibitors
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	11
	Me-too status	Protorib Tablet by Helix
	GMP status	The last inspection conducted on 31-01-2022 and report
	Remarks of the Evaluator ³ .	concludes that overall GMP compliance was found good.
	Remarks of the Evaluator.	• Revise your label claim along with submission of full fee as per the innovator's product as per following:
		Each Enteric Coated Tablet Contains:
		Rabeprazole Sodium20mg
	Decision: Approved with Innovator's s	pecifications and with following label claim:
	Each Enteric Coated Tab	
	Rabeprazole Sodium20	
		s. 30,000/- for correction/pre-approval change in product label claim
	as per notification No.F./-11/2	012-B&A/DRAP dated 07-05-2021, before issuance of registration
220.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
220.	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Tindo 2mg Tablet
	Composition	Each Tablet Contains:
		Tizanidine (as HCl)2mg
	Diary No. Date of R& I & fee	Dy No. 14801: 07-03-2019
	Dhamas a la sia al Cusus	PKR 20,000/-: 28-02-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form Finished Product Specification	Form 5 USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Movax Tablet by Sami
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	•
221.	Decision: Approved. Name and address of manufacturer /	M/s Winthway I shoustoning Dut I td V 210/A C I T E Compa
221.	Applicant	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Tranza Injection 500mg
	Composition	Each ml Contains:
	•	Tranexamic Acid500mg
	Diary No. Date of R& I & fee	Dy No. 14643: 07-03-2019
	Di la	PKR 20,000/-: 04-03-2019
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished Product Specification Pack size & Demanded Price	JP As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	with Approved
	Me-too status	Tranxet Injection by Bio-Labs
	GMP status	The last inspection conducted on 31-01-2022 and report
	_	concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	• Firm has liquid injectable (general) section.
		• Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each 5ml ampoule Contains: Tranexamic Acid500mg
	Decision: Approved with following laborates	
	Each 5ml ampoule Conta	

Tranexamic Acid...500mg

• The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

222.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Tranza Injection 250mg
	Composition	Each ml Contains:
		Tranexamic Acid250mg
	Diary No. Date of R& I & fee	Dy No. 14642: 07-03-2019
		PKR 20,000/-: 28-02-2019
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Could not be confirmed
	Regulatory Authorities.	
	Me-too status	Could not be confirmed
	GMP status	The last inspection conducted on 31-01-2022 and report
		concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	• Firm has liquid injectable (general) section.
		Evidence of approval of applied formulation in reference regulatory
		authorities/agencies which were adopted by the Registration Board in
		its 275th meeting.
		Evidence of applied formulation/drug already approved by DRAP
		(generic / me-too status) alongwith registration number, brand name
		and name of firm

Decision: Deferred for following:

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

. Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
Applicant	Highway, Phase-II, Karachi, Pakistan
Brand Name +Dosage Form + Strength	Wapival 250mg Tablet
Composition	Each Enteric Coated Tablet Contains:
	Valproate Semisodium250mg
Diary No. Date of R& I & fee	Dy No. 14804: 07-03-2019
	PKR 20,000/-: 28-02-2019
Pharmacological Group	Antiepileptic
Type of Form	Form 5
Finished Product Specification	BP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	MHRA Approved
Regulatory Authorities.	
Me-too status	Epival Tablet by Abbott
GMP status	The last inspection conducted on 31-01-2022 and report
	concludes that overall GMP compliance was found good.
Remarks of the Evaluator ³ .	Revise your label claim along with submission of full fee as per the
	innovator's product as per following:
	Each Enteric Coated Tablet Contains:
	Valproate Semisodium eq to valproic acid250mg

Decision: Approved with following label claim:

Each Enteric Coated Tablet Contains:

Valproate Semisodium eq to valproic acid...250mg

224.	Name and address of manufacturer /	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super
	Applicant	Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Wapival 500mg Tablet
	Composition	Each Enteric Coated Tablet Contains:

		Valproate Semisodium500mg
	Diary No. Date of R& I & fee	Dy No. 14805: 07-03-2019
	•	PKR 20,000/-: 04-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Epival Tablet by Abbott
	GMP status	The last inspection conducted on 31-01-2022 and report
	SIII SIIII	concludes that overall GMP compliance was found good.
	Remarks of the Evaluator ³ .	Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each Enteric Coated Tablet Contains:
		Valproate Semisodium eq to valproic acid500mg
	Decision: Approved with following labe	
	Each Enteric Coated Tab	
	Valproate Semisodium eq	to valproic acid500mg
		s. 30,000/- for correction/pre-approval change in product label claim
		012-B&A/DRAP dated 07-05-2021, before issuance of registration
	letter.	,
225.	Name and address of manufacturer /	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5,
	Applicant	National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Coartem DS Tablet
	Composition	Each Tablet Contains:
	•	Artemether40mg
		Lumefantrine240mg
	Diary No. Date of R& I & fee	Dy No. 13335: 07-03-2019
	•	PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	Ph. Int.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	WHO PQ formulation
	Regulatory Authorities.	
	Me-too status	Artem DS Plus Tablet by Hilton
	GMP status	•
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		years.
	Decision: Approved.	
		ed after submission of updated GMP inspection report by the firm.
226.	Name and address of manufacturer /	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5,
	Applicant	National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Riclofen 10mg Tablet
	Composition	Each Film Coated Tablet Contains:
	1	Baclofen10mg
	Diary No. Date of R& I & fee	Dy No. 13345: 07-03-2019
	·	PKR 20,000/-: 07-03-2019
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	11
	Me-too status	Baclofa Tablet by Helix
	GMP status	
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
	Remarks of the Livatuator.	years.
		Revise your label claim along with submission of 7500 fee as per the
		innovator's product as per following:
		innovator a product as per ronowing.

		Each Tablet Contains:
	Design Annuared with following labor	Baclofen10mg
	Decision: Approved with following laboration: Each Tablet Contains:	et ctann:
	Baclofen10mg	
		vision of formulation from film coated tablet to uncoated tablet as
	per notification No.F.7-11/2012-B&	
227.	Name and address of manufacturer /	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5,
	Applicant	National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	D Lorin 5mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Desloratadine5mg
	Diary No. Date of R& I & fee	Dy No. 13319: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities. Me-too status	Destina Tablet by Hilton
		Destina Tablet by Hilton
	GMP status	Y and GIRD in the control of the con
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three
	Decision: Approved.	years.
		ad after submission of undated CMD inspection report by the firm
228.	Name and address of manufacturer /	ed after submission of updated GMP inspection report by the firm. M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5,
220.	Applicant	National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Ezestatin-2 Tablet
	Composition	Each Film Coated Tablet Contains:
	- Confession	Ezetimibe10mg
		Simvastatin20mg
	Diary No. Date of R& I & fee	Dy No. 13361: 07-03-2019
	-	PKR 20,000/-: 07-03-2019
	Pharmacological Group	HMG CoA reductase inhibitors in combination with other
		lipid modifying agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Simvax Plus Tablet by Evolution pharma
	GMP status	
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		years.
		• Revise your label claim along with submission of 7500 fee as per the
		innovator's product as per following: Each Tablet Contains:
		Ezetimibe10mg
		Simvastatin20mg
	Decision: Approved with Innovator's s	pecifications and with following label claim:
	Each Tablet Contains:	The same and a same
	Ezetimibe10mg	
	Simvastatin20mg	
		evision of formulation from film coated tablet to uncoated tablet as
	per notification No.F.7-11/2012-Bo	
229.	Name and address of manufacturer /	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5,
	Applicant	National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Wystaglobin Chewable Tablet
	Composition	Each Chewable Tablet Contains:
		Iron III Hydroxide Polymaltose Complex Eq. To Elemental
1		Iron100mg

		Folic Acid0.35mg
	Diary No. Date of R& I & fee	Dy No. 13347: 07-03-2019
	•	PKR 20,000/-: 07-03-2019
	Pharmacological Group	Hematinic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Fersip Fol Chewable Tablet by Scotmann Pharma
	GMP status	
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
		• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275 th meeting.
		ed after submission of updated GMP inspection report by the firm. or revision of specifications as per notification No.F.7-11/2012-
230.	Name and address of manufacturer /	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5,
250.	Applicant	National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Arrefloxacin 500mg Tablet
	Composition	Each Film Coated Tablet Contains:
	•	Levofloxacin As Hemihydrate500mg
	Diary No. Date of R& I & fee	Dy No. 13367: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Leflox Tablet by Getz Pharma
	GMP status	
	Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved.	
	Registration letter will be issue	ed after submission of updated GMP inspection report by the firm.
231.	Name and address of manufacturer /	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5,
	Applicant	National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Lorin 5mg Tablet
	Composition	Each Film Coated Tablet Contains:
		Loratadine5mg
	Diary No. Date of R& I & fee	Dy No. 13320: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiallergic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three years.
		• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

Evidence of applied formulation/drug already approved by DRAP
(generic / me-too status) alongwith registration number, brand name
and name of firm

Decision: Deferred for following:

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
- Latest GMP inspection report conducted within a period of last three years.

2. Name and address of manufacturer /	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5,
Applicant	National Industrial Zone, Rawat, Rawalpindi
Brand Name +Dosage Form + Strength	Pantazol 40mg Tablet
Composition	Each Enteric Coated Tablet Contains:
	Pantoprazole Sodium Eq. To Pantoprazole40mg
Diary No. Date of R& I & fee	Dy No. 13372: 07-03-2019
	PKR 20,000/-: 07-03-2019
Pharmacological Group	Proton Pump Inhibitors
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	MHRA Approved
Regulatory Authorities.	
Me-too status	Protium Tablet by Abbott
GMP status	
Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three years.
	• Revise your label claim along with submission of full fee as per the innovator's product as per following:
	Each Enteric Coated Tablet Contains:
	Pantoprazole (as sodium sesquihydrate)40mg

Decision: Approved with following label claim:

Each Enteric Coated Tablet Contains:

Pantoprazole (as sodium sesquihydrate).....40mg

- Registration letter will be issued after submission of updated GMP inspection report by the firm.
- The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

Name and address of manufacturer /	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5,
Applicant	National Industrial Zone, Rawat, Rawalpindi
Brand Name +Dosage Form + Strength	Arrexan 200mg Tablet
Composition	Each Film Coated Tablet Contains:
	Rifaximin200mg
Diary No. Date of R& I & fee	Dy No. 13335: 07-03-2019
	PKR 20,000/-: 07-03-2019
Pharmacological Group	Antibiotics
Type of Form	Form 5
Finished Product Specification	BP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	MHRA Approved
Regulatory Authorities.	
Me-too status	Axibol Tablet by Genetics Pharma
GMP status	
Remarks of the Evaluator ³ .	• Latest GMP inspection report conducted within a period of last three

Registration letter will be issued after submission of updated GMP inspection report by the firm.

234.	Name and address of manufacturer /	M/s Skims Pharmaceuticals, 10/B Value Addition city,
	Applicant	Khurrianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Skicon Capsule 150mg
	Composition	Each Capsule Contains:
	_	Fluconazole150mg

	Diary No. Date of R& I & fee	Dy No. 16426: 07-03-2019
		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antimycotics for systemic use
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Candizole Capsule by Genetics Pharma
	GMP status	
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
		vears.
	Decision: Approved.	yours
		ued after submission of updated GMP inspection report by the firm.
235.	Name and address of manufacturer /	M/s Skims Pharmaceuticals, 10/B Value Addition city,
200.	Applicant	Khurrianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Skical Sachet
	Composition	Each Sachet Contains:
	Composition	Calcium Carbonate685mg
		Calcium Gluconate20mg
		Calcium Lactate200mg
		Asorbic Acid500mg
	Diary No. Date of R& I & fee	Dy No. 16425: 07-03-2019
	Blary 1vo. Bate of Ree 1 te 1ee	PKR 20,000/-: 07-03-2019
	Pharmacological Group	Calcium + Vitamin
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
		Could not be confirmed
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Genzit Sachet 685/20/200/500mg by Rogen Pharma
	GMP status	Genzit Sacrict 003/20/200/300mg by Rogen Filanna
	Remarks of the Evaluator ³ .	Latest GMP inspection report conducted within a period of last three
	Remarks of the Evaluator .	years.
		Evidence of approval of applied formulation in reference regulatory
		authorities/agencies which were adopted by the Registration Board in
		its 275th meeting.
	Decision: Deferred for following submi	
		d formulation in reference regulatory authorities/agencies which were
	adopted by the Registration Be	
		conducted within a period of last three years.
236.	Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
250.	Applicant	Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Kacinon Injection 100mg/2ml
	Composition	Each 2ml Contains:
	Composition	Amikacin as Sulphate1000mg
	Diary No. Date of R& I & fee	Dy No. 15123: 07-03-2019
	Diary No. Date of Rec 1 & Ice	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other aminoglycosides
	Type of Form	Form 5
	Finished Product Specification Pack size & Demanded Price	USP
		As per SRO
	Approval status of product in Reference	Could not be confirmed
	Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
	I	of inspection dated 10-01-2022
	D 1 01 - 1 2	•
	Remarks of the Evaluator ³ .	Evidence of required manufacturing facility / section approval letter from Licensing Division.

- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm

Decision: Deferred for following:

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

• Evidence of required manufacturing facility / section approval letter from Licensing Division.

237.	Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
	Applicant	Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Kacinon Injection 250mg/2ml
	Composition	Each 2ml Contains:
	_	Amikacin as Sulphate250mg
	Diary No. Date of R& I & fee	Dy No. 15124: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other aminoglycosides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Could not be confirmed
	Regulatory Authorities.	
	Me-too status	Could not be confirmed
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 10-01-2022
	Remarks of the Evaluator ³ .	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
		• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
		Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm

Decision: Deferred for following:

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

Evidence of required manufacturing facility / section approval letter from Licensing Division.

238.	Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
	Applicant	Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Lexim 125mg/ml Dry Powder suspension
	Composition	Each 5ml of reconstituted suspension contains:
		Cephalexin monohydrate125mg
	Diary No. Date of R& I & fee	Dy No. 15147: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved.
	Regulatory Authorities.	
	Me-too status	Keflex suspension by AGP
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 10-01-2022
	Remarks of the Evaluator ³ .	• Firm has dry powder suspension (cephalosporin) section as per the
		GMP certificate issued on the basis of inspection dated 10-01-2022.

	• Revise your label claim along with submission of full fee as per the
	innovator's product as per following:
	Each 5ml of reconstituted suspension contains:
	Cephalexin (as monohydrate)125mg

Decision: Approved with following label claim:

Each 5ml of reconstituted suspension contains:

Cephalexin (as monohydrate)...125mg

• The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

239.	Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
	Applicant	Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Lexim 250mg/ml Dry Powder suspension
	Composition	Each 5ml of reconstituted suspension Contains:
		Cephalexin Monohydrate250mg
	Diary No. Date of R& I & fee	Dy No. 15137: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved.
	Regulatory Authorities.	
	Me-too status	Keflex suspension by AGP
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 10-01-2022
	Remarks of the Evaluator ³ .	• Firm has dry powder suspension (cephalosporin) section as per the
		GMP certificate issued on the basis of inspection dated 10-01-2022.
		• Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each 5ml of reconstituted suspension contains:
		Cephalexin (as monohydrate)250mg
	Decision: Approved with following labor	al claim:

Decision: Approved with following label claim:

Each 5ml of reconstituted suspension contains:

Cephalexin (as monohydrate)...250mg

	ictici.	
240.	Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
	Applicant	Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Emycin 125mg Granules
	Composition	Each 5ml of reconstituted suspension contains:
		Erythromycin125mg
	Diary No. Date of R& I & fee	Dy No. 15138: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	
	Me-too status	Xyrox-E 125mg Dry Suspension by Jawa Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 10-01-2022
	Remarks of the Evaluator ³ .	• Firm has dry powder suspension (General) section as per the GMP
		certificate issued on the basis of inspection dated 10-01-2022.
		• Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each 5ml of reconstituted suspension contains:
		Erythromycin (as ethyl succinate)125mg
	Decision: Approved with following labe	el claim:
	Each 5ml of reconstituted	suspension contains:

Erythromycin (as ethyl succinate)...125mg

• The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

241.	Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
	Applicant	Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Emycin 200mg Granules
	Composition	Each 5ml Contains:
		Erythromycin200mg
	Diary No. Date of R& I & fee	Dy No. 15129: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Eryped granules for oral suspension of Abror Pharms
	Regulatory Authorities.	(USFDA approved)
	Me-too status	Eryget 200mg/5ml (Granules) Suspension by Getz
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 10-01-2022
	Remarks of the Evaluator ³ .	• Firm has dry powder suspension (General) section as per the GMP
		certificate issued on the basis of inspection dated 10-01-2022.
		Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each 5ml of reconstituted suspension contains:
		Erythromycin (as ethyl succinate)200mg

Decision: Approved with following label claim:

Each 5ml of reconstituted suspension contains:

Erythromycin (as ethyl succinate)...200mg

• The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
Applicant Drand Name Dasses Form Strongth	Highway Karachi, Pakistan
Brand Name +Dosage Form + Strength	Biofen Tablet 50mg
Composition	Each Film Coated Tablet Contains:
	Flurbiprofen50mg
Diary No. Date of R& I & fee	Dy No. 15134: 07-03-2019
	PKR 20,000/-: 06-03-2019
Pharmacological Group	NSAID
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference	MHRA Approved
Regulatory Authorities.	
Me-too status	Dynasaid 50mg Tablets by Dynatis
GMP status	Firm has submitted copy of GMP certificate issued on the basis
	of inspection dated 10-01-2022
Remarks of the Evaluator ³ .	• Revise your label claim along with submission of 7500 fee as per the
	innovator's product as per following:
	Each Sugar Coated Tablet Contains:
	Flurbiprofen50mg
Decision: Approved with following lab	

Decision: Approved with following label claim:

Each Sugar Coated Tablet Contains:

Flurbiprofen...50mg

• Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to sugar coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

243. Name and address of manufacturer / Applicant Highway Karachi, Pakistan

Brand Name +Dosage Form + Strength Composition Each Film Coated Tablet Contains:
Levofloxacin Hemihydrate eq to Levofloxacin Base...250mg

	Diam No Data of D 0 I 0 for	D. N. 15125, 07 02 2010
	Diary No. Date of R& I & fee	Dy No. 15135: 07-03-2019
	DI 1 1 G	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	
	Me-too status	Leflox Tablet by Getz Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 10-01-2022
	Remarks of the Evaluator ³ .	•
	Decision: Approved.	
244.	Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
	Applicant	Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Elvox Tablet 500mg
	Composition	Each Film Coated Tablet Contains:
		Levofloxacin Hemihydrate eq to Levofloxacin Base500mg
	Diary No. Date of R& I & fee	Dy No. 15146: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	OSI DA Appioved
	Me-too status	Leflox Tablet by Getz Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
	OWI Status	
	D 1 C1 E 1 3	of inspection dated 10-01-2022
	Remarks of the Evaluator ³ .	•
245	Decision: Approved.	M/ M/ · DI / · I D / I / DI / N / A CUETE C
245.	Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
245.	Name and address of manufacturer / Applicant	Highway Karachi, Pakistan
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Highway Karachi, Pakistan Elvox Tablet 750mg
245.	Name and address of manufacturer / Applicant	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains:
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities.	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved.	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
245.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ .	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer /	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022 M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022 M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022 M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan Unicocin Injection 300mg/ml
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022 M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan Unicocin Injection 300mg/ml Each ml Contains:
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022 M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan Unicocin Injection 300mg/ml Each ml Contains: Lincomycin HCl Monohydrate300mg
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022 M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan Unicocin Injection 300mg/ml Each ml Contains: Lincomycin HCl Monohydrate300mg Dy No. 15143: 07-03-2019
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022 M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan Unicocin Injection 300mg/ml Each ml Contains: Lincomycin HCl Monohydrate300mg Dy No. 15143: 07-03-2019 PKR 20,000/-: 06-03-2019
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 Evaluator³. Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022 M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan Unicocin Injection 300mg/ml Each ml Contains: Lincomycin HCl Monohydrate300mg Dy No. 15143: 07-03-2019 PKR 20,000/-: 06-03-2019 Antibiotic Form 5
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & 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 ³ . Decision: Approved. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Highway Karachi, Pakistan Elvox Tablet 750mg Each Film Coated Tablet Contains: Levifloxacin Hemihydrate eq to Levifloxacin Base750mg Dy No. 15120: 07-03-2019 PKR 20,000/-: 06-03-2019 Fluoroquinolones Form 5 USP As per SRO USFDA Approved Leflox Tablet by Getz Pharma Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022 • M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan Unicocin Injection 300mg/ml Each ml Contains: Lincomycin HCl Monohydrate300mg Dy No. 15143: 07-03-2019 PKR 20,000/-: 06-03-2019 Antibiotic

	Approval status of product in Reference	USFDA Approved (as 2ml vial)
	Regulatory Authorities.	PMDA Japan Approved (as 1ml)
	Me-too status	Linkotrex Injection by Wimits Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 10-01-2022
	Remarks of the Evaluator ³ .	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
		Specify the exact fill volume of the applied product.
		• Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each ml Contains:
	D	Lincomycin (as HCl Monohydrate)300mg
	Decision: Deferred for following submi	
		turing facility / section approval letter from Licensing Division.
		act fill volume of the applied product.
	 Revision of the formulation an full fee of registration. 	d label claim as per the innovator's product along with submission of
247.	Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
	Applicant	Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Entazolate Tablet 200/250mg
	Composition	Each Film Coated Tablet Contains:
	Composition	Metronidazole200mg
		Diloxanide Furoate250mg
	Diary No. Date of R& I & fee	Dy No. 15141: 07-03-2019
	Diary No. Date of Ree 1 & 1ee	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Nitroimidazole derivatives
	-	
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Mntazole Tablet by Jawa
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 10-01-2022
	Remarks of the Evaluator ³ .	Evidence of approval of applied formulation in reference regulatory
		authorities/agencies which were adopted by the Registration Board in
		its 275th meeting.
	Decision: Deferred for evidence of app	roval of applied formulation in reference regulatory
		ed by the Registration Board in its 275th meeting.
248.	Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
	Applicant	Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Entazole DS Tablet 400/500mg
	Composition	Each Film Coated Tablet Contains:
	_	Metronidazole400mg
		Diloxanide Furoate500mg
	Diary No. Date of R& I & fee	Dy No. 15136: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Nitroimidazole derivatives
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Could not be confirmed
	Regulatory Authorities.	
	Me-too status	Mntazole Tablet by Jawa
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 10-01-2022
	Remarks of the Evaluator ³ .	Evidence of approval of applied formulation in reference regulatory
	Temarks of the Dyarduoi .	authorities/agencies which were adopted by the Registration Board in
		its 275th meeting.
	Decision: Deferred for evidence of annu	roval of applied formulation in reference regulatory
		ed by the Registration Board in its 275th meeting.
	aumornies/agencies which were adopte	a by the Registration board in its 275th meeting.

240	N/	MI-M'
249.	Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
	Applicant	Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Cyclin M Capsule 50mg
	Composition	Each Capsule Contains:
		Minocycline HCl50mg
	Diary No. Date of R& I & fee	Dy No. 15126: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Tetracyclines
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	USFDA Approved
	Regulatory Authorities.	CSI DA Appioved
	Me-too status	My Cin Consula by Ciba Dharma
		My-Cin Capsule by Ciba Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 10-01-2022
	Remarks of the Evaluator ³ .	• Firm has capsule (General) section.
		Revise your label claim along with submission of full fee as per the
		innovator's product as per following:
		Each Capsule Contains:
		Minocycline (as HCl)50mg
	Decision: Approved with Innovator's s	pecifications and with following label claim:
	Each Capsule Contains:	pecifications and with following laber claim.
	Minocycline (as HCl)50	lma
	• The firm shall submit fee of Rs	s. 30,000/- for correction/pre-approval change in product label claim
		012-B&A/DRAP dated 07-05-2021, before issuance of registration
250	letter.	DECEMBER OF THE PROPERTY OF TH
250.	Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
	Applicant	Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Anakort 40mg Injection
	Composition	Each ml Contains:
		Triamcinolone Acetonide40mg
	Diary No. Date of R& I & fee	Dy No. 15133: 07-03-2019
	•	PKR 20,000/-: 06-03-2019
	Pharmacological Group	Glucocorticoid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities.	AT THE TOTAL OF TH
	Me-too status	Novacort injection by Novex Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis
		of inspection dated 10-01-2022
	Remarks of the Evaluator ³ .	Evidence of required manufacturing facility / section approval letter
		from Licensing Division.
		Specify the fill volume of the applied product.
	Decision: Deferred for following submi	
		turing facility / section approval letter from Licensing Division.
		act fill volume of the applied product.
251.	Name and address of manufacturer /	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super
251.		
	Applicant	Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Miszin 10mg/5ml
	Composition	Each 5ml Contains:
		Zinc Sulphate10mg
	Diary No. Date of R& I & fee	Dy No. 15139: 07-03-2019
		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other Mineral Supplements
	Type of Form	Form 5
	Finished Product Specification	Ph. Int.
	Pack size & Demanded Price	As per SRO
	Tata dide & Demanded Flice	1 per 2110

Approval status of product in Reference	Could not be confirmed in any RRA or NEML, Paediatric zinc sulfate
Regulatory Authorities.	oral solution monograph in international pharmacopoeia under the
	heading of Additional information specifies that "Available strengths:
	10 mg or 20 mg of zinc per 5 mL"
Me-too status	Zincbar Syrup by MBL Pharma
GMP status	Firm has submitted copy of GMP certificate issued on the basis
	of inspection dated 10-01-2022
Remarks of the Evaluator ³ .	• Revise your label claim along with submission of full fee as per the
	innovator's product as per following:
	Each 5ml Contains:
	Zinc (as Sulphate monohydrate)10mg
Decision: Approved with following label claim:	
Each 5ml Contains:	
Zinc (as Sulphate monohydrate)10mg	

252.	Name and address of	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super
	manufacturer / Applicant	Highway, Phase II, Karachi
	Brand Name + Dosage Form +	Fetrex Gel 0.025%
	Strength	
	Composition	Each Gm of Gel Contains:
		Fluocinolone Actonide 0.25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13561 dated 07-03-2019 Rs.20,000 dated 06-03-
		2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Could not be confirmed
	Reference Regulatory Authorities	
	Me-too status (with strength and	043445; "DERMOLONE GEL 0.025%"
	dosage form)	"VEGA."
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator:	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory	
		lopted by the Registration Board in its 275 th meeting.
253.	Name and address of	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super
	manufacturer / Applicant	Highway, Phase II, Karachi
	Brand Name + Dosage Form +	Bifyllin 600mg Film Coated Tablet
	Strength	
	Composition	Each Film Coated Tablet Contains:
		Bamifylline (As Hydrochloride) 600mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13539 dated 07-03-2019 Rs.20,000 dated 06-03-
		2019
	Pharmacological Group	Methylxanthine
	Type of Form	Form-5
	Finished product Specifications	Maxitech Pharma
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Could not be confirmed
	Reference Regulatory Authorities	
	Me-too status (with strength and	014936; "BAMIFIX 600mg Tablet"
	dosage form)	"Cheisi Pharma."
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator:	
ļi		
	Decision: Deferred for evidence of	of approval of applied formulation in reference regulatory lopted by the Registration Board in its 275 th meeting.

254.	Name and address of manufacturer / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi	
	Brand Name + Dosage Form +	Andar-H 16mg + 12.5mg Tablet	
	Strength	Alidat-11 Tollig + 12.5llig Tablet	
	Composition	Each Tablet Contains:	
	Composition	Candesartan Cilexetil16mg	
		Hydrochlorothiazide12.5mg	
	Diary No. Date of R& I & fee	Form-5 Dy.No 13529 dated 07-03-2019 Rs.20,000 dated 06-03-	
		2019	
	Pharmacological Group	Anti-Hypertensive	
	Type of Form	Form-5	
	Finished product Specifications	USP Specification	
	Pack size & Demanded Price	As per SRO	
	Approval status of product in	ATACAND HCT®	
	Reference Regulatory Authorities	USFDA Approved.	
	Me-too status (with strength and	034675; "CANSAAR PLUS 16mg+12.5mg Tablet"	
	dosage form)	"Abbott Pharm."	
	GMP status	GMP certificate issued on 31.08.2022	
	Remarks of Evaluator:		
	Decision: Approved with following		
	Each Film Coated Tablet Co		
	Candesartan Cilexetil1 Hydrochlorothiazide1		
		or revision of formulation from uncoated tablet to film coated	
	I	7-11/2012-B&A/DRAP dated 07-05-2021.	
255.	Name and address of	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super	
255.	manufacturer / Applicant	Highway, Phase II, Karachi	
	Brand Name + Dosage Form +	Fetrex Ointment 0.025%	
	Strength	3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	
	Composition	Each Gm of Ointment Contains:	
	1	Fluocinolone Acetonide 0.25mg	
	Diary No. Date of R& I & fee	Form-5 Dy.No 13560 dated 07-03-2019 Rs.20,000 dated 06-03-	
		2019	
	Pharmacological Group	Corticosteroid	
	Type of Form	Form-5	
	Finished product Specifications	USP Specification	
	Pack size & Demanded Price	As per SRO	
	Approval status of product in	SYNALAR®	
	Reference Regulatory Authorities	USFDA Approved.	
	Me-too status (with strength and	041892; "DERMOLONE OINTMENT 0.025%"	
	dosage form) GMP status	"VEGA."	
	Remarks of Evaluator:	GMP certificate issued on 31.08.2022	
	Decision: Approved.		
256.	Name and address of	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super	
200.	manufacturer / Applicant	Highway, Phase II, Karachi	
	Brand Name + Dosage Form +	D-Light 50000 soft Gelatin Capsule	
	Strength		
	Composition	Each Soft Gelatin Capsule Contains:	
		Vitamin D350000IU	
	Diary No. Date of R& I & fee	Form-5 Dy.No 13570 dated 07-03-2019 Rs.20,000 dated 06-03-	
		2019	
	Pharmacological Group	Vitamin	
	Type of Form	Form-5	
	Finished product Specifications	Firm has claimed in house specifications	
	Pack size & Demanded Price	As per SRO	

	Approval status of product in	Altavita D3 50000 iu soft capsules		
	Reference Regulatory Authorities	HPRA		
	Me-too status (with strength and	097598; "HUESO-D 50000IU SOFT GELATIN CAPSULE"		
	dosage form)	"VALOR/AL-HAMEED"		
	GMP status	GMP certificate issued on 31.08.2022		
	Remarks of Evaluator:			
	Decision: Deferred for confirmation Division.	n of required manufacturing facility / section from Licensing		
257.	Name and address of	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super		
257.	manufacturer / Applicant	Highway, Phase II, Karachi		
	Brand Name + Dosage Form +	Bitrex 4% Cream		
	Strength	Butex 470 Cream		
	Composition	Each 100Gm Cream Contains:		
	Composition	Benzoyl Peroxide 4g		
	Diary No. Date of R& I & fee	Form-5 Dy.No 13565 dated 07-03-2019 Rs.20,000 dated 06-03-		
	Diary No. Date of R& 1 & fee	2019		
	Dharmanalagigal Crown			
	Pharmacological Group	organic compounds		
	Type of Form	Form-5		
	Finished product Specifications	Maxitech Specification		
	Pack size & Demanded Price	As per SRO		
	Approval status of product in	Could not be confirmed		
	Reference Regulatory Authorities	040464 #PPPYYOYYY 404 G		
	Me-too status (with strength and	019464; "BREVOXYL 4% Cream"		
	dosage form)	"GSK"		
	GMP status	GMP certificate issued on 31.08.2022		
	Remarks of Evaluator:			
Decision: Deferred for evidence of approval of applied formulation in reference authorities / agencies which were adopted by the Registration Board in its 275 th meeting				
258.	Name and address of			
250.		M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super		
250.	manufacturer / Applicant	Highway, Phase II, Karachi		
250.	manufacturer / Applicant Brand Name + Dosage Form +			
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength	Highway, Phase II, Karachi Fetrex Topical Solution 0.01%		
250.	manufacturer / Applicant Brand Name + Dosage Form +	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains:		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status (with strength and	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status (with strength and	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status (with strength and dosage form)	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed Could not be confirmed		
250.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status (with strength and dosage form) GMP status	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed Could not be confirmed		
	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status (with strength and dosage form) GMP status Remarks of Evaluator: Decision: Deferred for following:	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed Could not be confirmed		
	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status (with strength and dosage form) GMP status Remarks of Evaluator: Decision: Deferred for following:	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed Could not be confirmed GMP certificate issued on 31.08.2022		
	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status (with strength and dosage form) GMP status Remarks of Evaluator: Decision: Deferred for following: • Evidence of applied formulation alongwith registration number,	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed Could not be confirmed GMP certificate issued on 31.08.2022		
	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status (with strength and dosage form) GMP status Remarks of Evaluator: Decision: Deferred for following: • Evidence of applied formulation alongwith registration number,	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed Could not be confirmed GMP certificate issued on 31.08.2022 on/drug already approved by DRAP (generic / me-too status) brand name and name of firm. formulation in reference regulatory authorities/agencies which		
259.	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status (with strength and dosage form) GMP status Remarks of Evaluator: Decision: Deferred for following: • Evidence of applied formulation alongwith registration number, • Evidence of approval of applied	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed Could not be confirmed GMP certificate issued on 31.08.2022 on/drug already approved by DRAP (generic / me-too status) brand name and name of firm. formulation in reference regulatory authorities/agencies which		
	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status (with strength and dosage form) GMP status Remarks of Evaluator: Decision: Deferred for following: • Evidence of applied formulation alongwith registration number, • Evidence of approval of applied were adopted by the Registration	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed Could not be confirmed GMP certificate issued on 31.08.2022 on/drug already approved by DRAP (generic / me-too status) brand name and name of firm. formulation in reference regulatory authorities/agencies which on Board in its 275th meeting.		
	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status (with strength and dosage form) GMP status Remarks of Evaluator: Decision: Deferred for following: • Evidence of applied formulation alongwith registration number, • Evidence of approval of applied were adopted by the Registration Name and address of	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed Could not be confirmed GMP certificate issued on 31.08.2022 on/drug already approved by DRAP (generic / me-too status) brand name and name of firm. formulation in reference regulatory authorities/agencies which on Board in its 275th meeting. M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super		
	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status (with strength and dosage form) GMP status Remarks of Evaluator: Decision: Deferred for following: Evidence of applied formulation alongwith registration number, Evidence of approval of applied were adopted by the Registration Name and address of manufacturer / Applicant	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed Could not be confirmed GMP certificate issued on 31.08.2022 on/drug already approved by DRAP (generic / me-too status) brand name and name of firm. formulation in reference regulatory authorities/agencies which on Board in its 275th meeting. M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi		
	manufacturer / Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specifications Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status (with strength and dosage form) GMP status Remarks of Evaluator: Decision: Deferred for following: • Evidence of applied formulation alongwith registration number, • Evidence of approval of applied were adopted by the Registration Name and address of manufacturer / Applicant Brand Name + Dosage Form +	Highway, Phase II, Karachi Fetrex Topical Solution 0.01% Each ml Contains: Fluocinolone Acetonide 0.1mg Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019 Corticosteroid Form-5 USP Specification As per SRO Could not be confirmed Could not be confirmed GMP certificate issued on 31.08.2022 on/drug already approved by DRAP (generic / me-too status) brand name and name of firm. formulation in reference regulatory authorities/agencies which on Board in its 275th meeting. M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi		

Cyclosporin 25mg					
	0.000 1-4-106 02				
Diary No. Date of R& I & fee Form-5 Dy.No 13568 dated 07-03-2019 Rs.20	0,000 dated 06-03-				
2019					
Pharmacological Group Immunosuppressant					
Type of Form Form-5					
Finished product Specifications USP Specification					
Pack size & Demanded Price As per SRO					
Approval status of product in Sandimmune® Soft Gelatin Capsule					
Reference Regulatory Authorities USFDA Approved.					
Me-too status (with strength and Sandimum soft Gelatin Capsules					
dosage form) NOVARTIS					
GMP status GMP certificate issued on 31.08.2022					
Remarks of Evaluator:					
Decision: Deferred for confirmation of required manufacturing facility / section	on from Licensing				
Division.	on Hom Licensing				
260. Name and address of M/s Maxitech Pharma Pvt Ltd. Plot No. E-1	178 SITE Super				
manufacturer / Applicant Highway, Phase II, Karachi	170, 5.1.1.E. Super				
Brand Name + Dosage Form + TH-SALIC Topical Solution					
Strength + Dosage Form + 111-SALIC Topical Solution					
Composition Each ml Contains:					
Conflosition Each in Contains. Coal Tar30mg					
Hydrocortisone10mg					
Salicylic Acid30mg	0.000.1 . 1.06.02				
Diary No. Date of R& I & fee Form-5 Dy.No 13545 dated 07-03-2019 Rs.20	0,000 dated 06-03-				
2019					
Pharmacological Group Corticosteroid					
Type of Form Form-5					
Finished product Specifications Maxitech Specification					
Pack size & Demanded Price As per SRO					
Approval status of product in Could not be confirmed					
Reference Regulatory Authorities					
Me-too status (with strength and "COSALIC LOTION"					
dosage form) "CRYSTOLITE"					
GMP status GMP certificate issued on 31.08.2022					
Remarks of Evaluator:					
Decision: Deferred for evidence of approval of applied formulation in reference regulatory					
authorities / agencies which were adopted by the Registration Board in its 275th					
261. Name and address of M/s Maxitech Pharma Pvt Ltd. Plot No. E-					
manufacturer / Applicant Highway, Phase II, Karachi	· -				
Brand Name + Dosage Form + Vartan S 24/26mg Tablet					
Strength					
Composition Each Film Coated Tablet Contains:					
Valsartan 24mg					
Sacubotril 26mg					
Diary No. Date of R& I & fee Form-5 Dy.No 13535 dated 07-03-2019 Rs.20					
	0,000/- dated 06-				
03-2019	0,000/- dated 06-				
Pharmacological Group Antihypertensive	0,000/- dated 06-				
Pharmacological Group Antihypertensive	0,000/- dated 06-				
Pharmacological Group Antihypertensive Type of Form Form-5	0,000/- dated 06-				
Pharmacological Group Antihypertensive Type of Form Form-5 Finished product Specifications As Per innovator Specification	0,000/- dated 06-				
Pharmacological Group Antihypertensive Type of Form Form-5 Finished product Specifications As Per innovator Specification Pack size & Demanded Price As per SRO	0,000/- dated 06-				
Pharmacological Group Antihypertensive Type of Form Form-5 Finished product Specifications As Per innovator Specification Pack size & Demanded Price As per SRO Approval status of product in Entresto®	0,000/- dated 06-				
Pharmacological Group Type of Form Form-5 Finished product Specifications Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities Antihypertensive Form-5 As Per innovator Specification As per SRO Entresto® USFDA Approved.	0,000/- dated 06-				
Pharmacological Group Type of Form Form-5 Finished product Specifications Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities Me-too status (with strength and ; "WILTRILL 24/20mg Tablet"	0,000/- dated 06-				
Pharmacological Group Type of Form Form-5 Finished product Specifications Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities USFDA Approved. Me-too status (with strength and dosage form) Antihypertensive Form-5 As Per innovator Specification Lentresto® USFDA Approved. ; "WILTRILL 24/20mg Tablet" "Helix Pharma"	0,000/- dated 06-				
Pharmacological Group Type of Form Form-5 Finished product Specifications Pack size & Demanded Price As per SRO Approval status of product in Reference Regulatory Authorities Me-too status (with strength and ; "WILTRILL 24/20mg Tablet"	0,000/- dated 06-				

	Decision: Deferred for submission of stability study data of three batches of drug product as per			
	the guidelines provided in 293 rd meeting of Registration Board.			
262.	Name and address of manufacturer / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi		
	Brand Name + Dosage Form + Strength	Fertrex N Cream 0.025%/0.5%		
	Composition	Each Gm Cream Contains:		
		Fluocinolone Acetonide 0.25mg		
		Neomycin Sulphate 5mg		
	Diary No. Date of R& I & fee	Form-5 Dy.No 13558 dated 07-03-2019 Rs.20,000/- dated 06-03-2019		
	Pharmacological Group	Corticosteroid		
	Type of Form	Form-5		
	Finished product Specifications	USP Specification		
	Pack size & Demanded Price	As per SRO		
	Approval status of product in	Could not be confirmed		
	Reference Regulatory Authorities	020220 DDEVOVVI 40/ G		
	Me-too status (with strength and dosage form)	029329; "BREVOXYL 4% Cream" "GSK"		
	GMP status	GMP certificate issued on 31.08.2022		
	Remarks of Evaluator:			
		of approval of applied formulation in reference regulatory		
		lopted by the Registration Board in its 275 th meeting.		
263.	Name and address of	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super		
	manufacturer / Applicant	Highway, Phase II, Karachi		
	Brand Name + Dosage Form + Strength	Cilone Cream 0.01%/4%/0.05%		
	Composition	Each Gm Cream Contains:		
		Fluocinolone Acetonide 0.1mg		
		Hydroquinone 40mg		
		Tretinoin 0.5mg		
	Diary No. Date of R& I & fee	Form-5 Dy.No 13555 dated 07-03-2019 Rs.20,000/- dated 06-03-2019		
	Pharmacological Group	Corticosteroid / Hydroxy quinolone / Antifungal		
	Type of Form	Form-5		
	Finished product Specifications	Maxitech Specification		
	Pack size & Demanded Price	As per SRO		
	Approval status of product in	TRI-LUMA Cream®		
	Reference Regulatory Authorities	USFDA Approved.		
	Me-too status (with strength and	071490; "TRIDERM Cream"		
	dosage form)	"Shrooq Pharma"		
	GMP status	GMP certificate issued on 31.08.2022		
	Remarks of Evaluator:			
	Decision: Approved with Innovator's specifications.			
	• 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.			
264.	Name and address of	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super		
	manufacturer / Applicant	Highway, Phase II, Karachi		
	Brand Name + Dosage Form + Strength	O Rice sachet		
	Composition	Each Sachet Contains:		
	r	Pre Cooked Rice Powder 6Gm		
		Sodium Chloride 0.350Gm		
		Potassium Chloride 0.580Gm		
		Sodium Citrate 0.300Gm		
	Diary No. Date of R& I & fee	Form-5 Dy.No 13576 dated 07-03-2019 Rs.20,000/- dated 06-		
		03-2019		

	Pharmacological Group	Electrolyte Replenisher	
	Type of Form	Form-5	
	Finished product Specifications	USP Specification	
	Pack size & Demanded Price	As per SRO	
	Approval status of product in	Could not be confirmed	
	Reference Regulatory Authorities		
Me-too status (with strength and		Hilyte-R powder sachet	
	dosage form)	Hilton Pharma	
	GMP status	GMP certificate issued on 31.08.2022	
	Remarks of Evaluator:		
	Decision: Deferred for following:		
		plied formulation in reference regulatory authorities/agencies	
	which were adopted by the	Registration Board in its 275th meeting.	
		anufacturing facility / section from Licensing Division.	
265.	Name and address of	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super	
	manufacturer / Applicant	Highway, Phase II, Karachi	
	Brand Name + Dosage Form +	Azetive Cream	
	Strength		
	Composition	Each Gm Cream Contains:	
		Azelaic Acid 0.2gm	
	Diary No. Date of R& I & fee	Form-5 Dy.No 13554 dated 07-03-2019 Rs.20,000/- dated 06-	
		03-2019	
	Pharmacological Group	Anti-microbial	
	Type of Form	Form-5	
	Finished product Specifications	Maxitech Specification	
	Pack size & Demanded Price	As per SRO	
	Approval status of product in	AZELEX Cream®	
	Reference Regulatory Authorities	USFDA Approved.	
	Me-too status (with strength and	012722; "SKINOREN Cream"	
	dosage form)	"Bayer"	
	GMP status	GMP certificate issued on 31.08.2022	
	Remarks of Evaluator:		
	Decision: Approved with Innovator	_	
		fee for revision of specifications as per notification No.F.7-	
	11/2012-B&A/DRAP dated	07-05-2021.	

Registration applications of CTD cases

a. Deferred cases of local manufacturing

Case No. 02

266.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat
	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 additional section dated 30-12-2020 for following 4 sections.

	_
	 Tablet (General) Capsule (General) Sachet (General) Oinment / Cream / Gel (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. 7362: 16-03-2022
Details of fee submitted	PKR 30,000/-: 14-01-2022
The proposed proprietary name / brand name	DEXZEN 30mg Capsule
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole (as dual delayed release pellets)30mg
Pharmaceutical form of applied drug	Small white round enteric coated pellets encapsulated in hard gelatin capsule
Pharmacotherapeutic Group of (API)	PPI
Reference to Finished product specifications	Manufacturer'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.	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance 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.

			manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of 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 Comparat	ive		
	Analytical method validati	on/verification of produc	et	Firm has submitted versubstance and the drug p	erification studies of the drug product.
		STABILITY	ST	UDY DATA	
Manufa	acturer of API	Vision Pharmaceuticals	s, P	lot No. 22-23, Industrial T	riangle Kahuta Road Islamabad.
API Lo	ot No.				
	ption of Pack iner closure system)	Alu-alu blister			
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 (M) Real Time: 0, 3, 6 (Mo)			
Batch l	No.	T-01		T-02	T-01
Batch S	Size	1200 Capsule		1200 Capsule	1200 Capsule
Manufa	acturing Date	02-2021		02-2021	02-2021
Date of	f Initiation	27-02-2021		27-02-2021	27-02-2021
No. of	Batches			03	
	DOCUMENTS / DAT	TA TO BE PROVIDED	A]	LONG WITH STABILI	TY STUDY DATA
	Reference of previous approtability study data of the firm		ith		
r	Approval of API/ DML/GMP certificate of API		Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad dated 31-07-2019. The GMP certificate was granted based on inspection dated 11-02-2019. The GMP certificate is valid till 10-02-2022.		
	Documents for the procurement of API with approval from DRAP (in case of import).		Firm has submitted copy of commercial invoice dated 23-02-2021 specifying purchase of 2Kg dexlansoprazole pellets 22.5%.		
r					
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing			heir HPLC system is not 21 CFR e audit trail reports are not	
l				ty monitoring of real time and	
Evalua	ntion by PEC ³ :				
•	GMP certificate / inspection report of the firm conducted within a period of last three years.				

- Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any method and procedures for preparation of each type of solution. Furthermore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.
- Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product, since you have submitted COA of multiple irrelevant batches in this section.
- Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis
 of drug substance / pellets along with its standardization record with the primary standard, since you have
 submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from
 that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other
 source of reference standard manufacturing.
- Section 3.2.S.6 specifies that the API manufacturer is using food grade double polyethylene bag for storing these pellets which are highly sensitive to moisture and light. Justification is required in this regard.
- Provide information in section 3.2.S.7.1 amd 3.2.S.7.2 as per CTD guidance document since you have only submitted stability data sheets in section 3.2.S.7 which is not in line with the Form 5-F as well as CTD guidance document.
- The stability study of dexlansoprazole pellets performed by Vision Pharmaceuticals specify that the pellets were stored in PET sealed bottles during stability studies while as per section 3.2.S.6 the packaging material of commercially manufactured pellets is food grade double polyethylene bag. Justify how these stability studies are applicable in this case and how it represents the true shelf life of the commercially manufactured pellets.
- Registration Board in its 276th meeting held on 22-25th November, 2017 reviewed the formulation of dexlansoprazole pellets wherein the representative from the pellets manufacturer appeared before the Board and admitted that previously they were not specifying testing of pellets at 5.5 pH in the COA. The submitted stability study data of the three batches of pellets manufactured in 2014 is submitted in which testing at pH 5.5 is also specified. Clarification is required in this regard.
- Submit complete information in section 3.2.P.1 as per form 5F without skipping any section or heading.
- Submit pharmaceutical equivalence report of the applied product along with reference / innovator's product in
 which all tests as per specifications shall be performed, since you have mentioned that pharmaceutical equivalence
 is not required and then you have also provided a brief report of dexlansoprazole tablet in which all tests are not
 performed.
- Provide complete report of comparative dissolution profile along with test parameters, analytical method and how
 the results are obtained and analysed, since you have only submitted tabulated and graphical representation
 without specifying any parameter.
- Submit information in section 3.2.P.3 as per the guidance document which specifies that "The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified".
- Provide information in section 3.2.P.3.2 as per the CTD guidance document which specifies that "A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards, since you have only submitted the same table which is already provided in section 3.2.P.1.
- Provide information in section 3.2.P.3.3 as per the CTD guidance document which specifies that "A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified. Proposals for the reprocessing of materials (if any) shall be justified. Any data to support this justification shall be provided in this section. The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified".

- Provide information in section 3.2.P.3.4 as per the CTD guidance document which specifies that "Tests and acceptance criteria shall be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process, to ensure that the process is controlled."
- Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established.
- Provide specifications of the drug product in section 3.2.P.5.1 along with submission of fee for revision of specifications since you have submitted Vision pharmaceuticals specifications of pellets in this section.
- Provide complete and analytical procedures of drug product in section 3.2.P.5.2 since you have provided analytical procedures of pellets in this section. Moreover, in assay test you have mentioned both UV and HPLC test. Clarification is required in this regard.
- Provide validation studies of the analytical method of drug product in section 3.2.P.5.3.
- Provide batch analysis certificate of three batches of drug product in section 3.2.P.5.4 where you have provided COA of dexlansoprazole pellets of Vision Pharmaceuticals with same results and your signatures after removing header containing name of Vision Pharmaceuticals.
- Provide COA of the reference standard / working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard.
- Provide information in section 3.2.P.7 as per the CTD guidance document which specifies that "A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided."
- You have mentioned white to off white pellets in section 3.2.P.1 while white and green pellets in section 3.2.P.8.1. Justification is required in this regard.
- Provide information in section 3.2.P.8.1 and 3.2.P.8.2 as per the Form 5F and CTD guidance document, since you have skipped these two sections and did not provide any information in these sections.
- Justify why only assay and dissolution test at one medium is performed in stability studies as evident from the submitted stability summary sheets.
- Your drug product specifications submitted in section 3.2.P.5.1 and specifications mentioned in COA of stability studies are different specifically in terms of dissolution test. Justify how you have performed stability studies without having any clear written specifications and analytical method.
- Justify the dissolution test in which the acceptance criteria is NLT 75% in 5 hours which is against the specificatiosn of innovator's product.
- Justify the dissolution acceptance criteria without specifying the value of Q as well as without identifying the criteria for analysis of results of dissolution test as per the criteria defined in USP general chapter <711> as well as defined by Registration Board in its 293rd meeting.
- Provide complete results of dissolution test including result of individual unit of capsule in the summary sheet or COA since results cannot be analysed without having results of individual units of the capsule.
- Provide stability study data in a proper sequence by providing stability summary sheet of individual batch along
 with proper separators to provide COA / raw data sheets along with HPLC chromatograms of standard and sample
 for the particular time point of that batch. Your submitted data is without any sequence, you have provided all
 COA and raw data sheets together and the rest of the data is also provided without proper sequence and sperators
 as per the guidelines of Registration Board. Submit your aligned data in a sequence so that further evaluation may
 be carried out.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
 - 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.
 - o Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
 - Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

Decision of 323rd meeting of Registration Board:

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

Response by the firm:

Sr. No	Short coming	Annexure
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01	GMP certificate /inspection report of the firm conducted within a period of last three years.	Firm has not submitted GMP certificate / inspection report.
02	Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.	Firm has not submitted QOS as per WHO template.
03	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted 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
04	Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any procedures for preparation of each type of solution. Furtherore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.	Firm has not submitted report of verification studies of the analytical method of drug substance performed by drug product manufacturer.
05	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product, since you have submitted COA of multiple irrelevant batches in this section.	Firm has submitted COA of batch number DLP664.
06	Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of hese pellets or any other source of reference standard manufacturing.	Firm has not sumitted COA of reference / working standard.
07	Section 3.2.S.6 specifies that the API food grade double manufacturer is using polyethylene bag for storing these which are pellets highly sensitive to moisture and light. Justification is required in this regard.	Three polyethylene bag used for packing of pellets. Two transparent and one black color bags along with silica gel.
08	Provide information in section 3.2.S.7.1 and 3.2.S.7.2 as CTD per guidance document since you have only submitted stability data sheets in section 3.2.S.7 which is not in line with the Form 5-F as well as CTD guidance document.	Firm has submitted information in section 3.2.S.7.1 and 3.2.S.7.2 as CTD per guidance document.
09	The stability study of Vision Dexlansoprazole pellets performed by Pharmaceuticals specify that the pellets were stored in PET sealed bottles during stability studies while as per section 3.2.S.6 the packaging material of commercially manufactured pellets is food grade double polyethylene bag. Justify how these stability studies are applicable in this case and how it represents the true shelf life of the commercially manufactured pellets.	Study performed at lab scale and in chamber they placed sample in pet bottle and for commercial they provide polythene bags and drum which is not possible in pet bottle.
10	Registration Board in its 276th meeting held on 22-25th November, 2017 reviewed the formulation of Dexlansoprazole pellets wherein the manufacturer appeared before the Board and admitted that previously they were not specifying testing of pellets at 5.5 pH in the COA. The submitted stability study data of the three batches of pellets manufactured in 2014 is submitted in which testing at pH 5.5 is also specified. Clarifications required in this regard.	DMF provided by vision pharma
11	Submit complete information in section 3.2.P.1 as per form 5F without skipping any section or heading.	Submitted by the firm.

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12	Submit pharmaceutical equivalence report of the applied product along with reference / innovator's product in which all tests as per specifications shall be performed, since you have mentioned that pharmaceutical equivalence is not required and then you have also provided a brief report of Dexlansoprazole tablet in which all tests are not performed.	Firm has submitted pharmaceutical equivalence studies against the comparator product manufactured by Weatherfolds pharma.
13	Provide complete report of comparative dissolution profile along with test parameters, analytical method and how the results are obtained and analysed, since you have only submitted tabulated and graphical representation without specifying any parameter	Firm has submitted results of comparative dissolution profile against the brand leader.
14	submit information in section 3.2.P.3 as per the guidance document which specifies that The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified"	Firm has submitted information in section 3.2.P.3 as per the guidance document.
15	Provide information in section 3.2.P.3.2 as per the CTD guidance document which specifies that "A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards, since you have only submitted the same table which is already provided in section 3.2.P.1	Firm has submitted information in section 3.2.P.3.2 as per the guidance document.
16	Provide information in section 3.2.P.3.3 as per the CTD guidance document which specifies that "A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified. Proposals for the reprocessing of materials (if any) shall be justified. Any data t supports this justification shall be provided in this section. The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified"	Firm has submitted information in section 3.2.P.3.3 as per the guidance document.
17	Provide information in section 3.2.P.3.4 as per the CTD guidance document which specifies that "Tests and acceptance criteria shall be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process, to ensure that the process is controlled."	Firm has submitted information in section 3.2.P.3.4 as per the guidance document.
18	Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established	Firm has not submitted process validation protocols.
19	Provide specifications of the drug product in section 3.2.P.5.1 along with submission of fee for revision of specifications since you have submitted Vision pharmaceuticals specifications of pellets in this section.	Firm has submitted specifications of the drug product in section 3.2.P.5.1.
20	provide complete and analytical procedures of drug product in section 3.2.P.5.2 since you have provided analytical procedures of pellets in this section. Moreover, in assay test you have mentioned both UV and HPLC test. Clarifications required in this regard	Firm has submitted specifications of the drug product in section 3.2.P.5.2.

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21	Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.	Firm has not submitted complete validation studies of the analytical method of drug product in section 3.2. P.5.3.
22	provide batch analysis certificate of three batches of drug product in section 3.2.P.5.4 where you have provided	Firm has submitted Batch analysis report of 3 stability batches.
	COA of Dexlansoprazole pellets of Vision	
	Pharmaceuticals with same results and your signatures	
	after removing header containing name of Vision Pharmaceuticals.	
23	Provide COA of the reference standard I working standard	Firm has not submitted COA of reference standard /
	in section 3.2.P.6 which is actually used in the analysis of	working standard.
	drug product along with its standardization record with the primary standard	
24	Provide information in section 3.2.P.7 as per the CTD	Firm has submitted details of container closure system.
	guidance document which specifies that "A detail of the	
	container closure systems, description of the primary	
	container closure systems, including materials of construction, unit count or fill size, container size or	
	volume shall be provided."	
25	You have mentioned white to off white pellets in section	Written mistakenly, revised and correct submitted.
	3.2.P.1 while white and green pellets in section 3.2.P.8.1.	,
	Justification is required in this regard	
26	Provide information in section 3.2.P.8.1 and 3.2.P.8.2 as	Firm has submitted information in section 3.2.P.8.1 and
	per the Form 5F and CTD guidance document, since you	3.2.P.8.2.
	have skipped these two sections and did not provide any information in these sections.	
27	justify why only assay and dissolution test at one medium	Firm has now submitted dissolution test results at different
27	is performed in stability studies as evident from the	medium in stability studies.
	submitted stability summary sheets	,
28	Your drug product specifications submitted in section	Firm has submitted specifications and analytical method
	3.2.P.5.1 and specifications mentioned in COA of stability	of drug product.
	studies are different specifically in terms of dissolution	
	test. Justify how you have performed stability studies	
	without having any clear written specifications and analytical method.	
29	justify the dissolution test in which the acceptance criteria	Typo mistake Revised COA attached
	NLT 75% in 5 hours which is against the specifications of	
	innovator's product	
30	justify the dissolution acceptance criteria without	Corrected and resubmitted by the firm
	specifying the value of Q as well as without identifying the criteria for analysis of results of dissolution test as per	
	the criteria defined in USP general chapter as well as	
	defined by Registration Board in its 293d meeting	
31	provide complete results of dissolution test including	Revised COA are submitted by the firm.
	result of individual unit of capsule in the summary sheet	·
	or COA since results cannot be analysed without having	
22	results of individual units of the capsule	Eine has submitted at 122 and to 1
32	provide stability study data in a proper se stability	Firm has submitted stability data in a proper sequence.
	summary sheet of individual batch along with proper separators to provide COA / raw data sheets along with	
	HPLC chromatograms of standard and sample for the	
	particular time point of that batch. Your submitted data is	
	without any sequence, you have provided all COA and	
	raw data sheets together and the rest of the data is also	
	provided without proper sequence and separators as per	
	the guidelines of Registration Board. Submit your aligned	
	data in a sequence so that further evaluation may be carried out	
33	submit stability study data in section 3.2.P.8.3 as per the	Firm has submitted response against the 6 points checklist
	checklist approved by Registration Board in its 296th	as per CTD guidance document.
	meeting and the CTD guidance document, which includes	
	the following:	
	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 both stability chambers	

Decision of 324th meeting: Deferred for following observations:

- Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.
- Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any procedures for preparation of each type of solution. Furtherore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.
- Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis
 of drug substance / pellets along with its standardization record with the primary standard, since you have
 submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from
 that specified in section 3.2.S.1 of your application and is neither the manufacturer of hese pellets or any other
 source of reference standard manufacturing.
- Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established
- Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.
- Provide COA of the reference standard I working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard

Firm's response:

Sr.#	Observation	Reply
1.	Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document	Submitted
2.	Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any procedures for preparation of each type of solution. Furtherore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.	Firm has submitted revised analytical method verification studies performed by M/s Wezen Pharmaceuticals.
3.	Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other source of reference standard manufacturing.	Firm has submitted COA of working standard form M/s Vision Pharmaceuticals.
4.	Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established	Firm has submitted revised process validation protocol including the critical steps, sampling plan, and evaluation criteria for the process of capsule filling, sealing and blistering.
5.	Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.	Submitted.

6.	Provide COA of the reference standard in working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard				
	on: Deferred for submission of Pharmaceutical ed against the innovator's product.	equivalence and Comparative Dissolution Profile (CDP)			
267.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat			
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat			
	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	has submitted copy of letter of grant of additional section dated 30-12-2020 for following 4 sections. • Tablet (General) • Capsule (General) • Sachet (General) • Oinment / Cream / Gel (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. 7363: 16-03-2022			
	Details of fee submitted	PKR 30,000/-: 14-01-2022			
	The proposed proprietary name / brand name	DEXZEN 60mg Capsule			
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole (as dual delayed release pellets)60mg			
l	Pharmaceutical form of applied drug	Small white round enteric coated pellets encapsulated in hard gelatin capsule			
	Pharmacotherapeutic Group of (API)	PPI			
	Reference to Finished product specifications	Manufacturer'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.	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. 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.			
	Module-III Drug Substan	nce:				
	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 24 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 Equivalence and Compara Dissolution Profile		e			
	Analytical method validation/verification of product		Firm has submitted verification studies of the drug substance and the drug product.			
		STABILITY	STUDY DATA			
Manuf	acturer of API	Vision Pharmaceuticals,	Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.			
API L	ot No.					
Description of Pack (Container closure system)		Alu-alu blister				
Stabili	ty 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				
Freque	ency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)				
Batch	No.	T-04	T-05	T-06		
Batch	Size	1200 Capsule	1200 Capsule	1200 Capsule		
Manufacturing Date		02-2021	02-2021	02-2021		
Date o	f Initiation	27-02-2021	27-02-2021	27-02-2021		
No. of	No. of Batches		03			
DOCUMENTS / DATA 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 issued by Additional Director DRAP, Islamabad dated 31-07-2019. The GMP certificate was granted based on inspection dated 11-02-2019. The GMP certificate is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 23-02-2021 specifying purchase of 2Kg dexlansoprazole pellets 22.5%.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm submitted that their HPLC system is not 21 CFR compliant therefore the audit trail reports are not applicable.
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC³:

- GMP certificate / inspection report of the firm conducted within a period of last three years.
- Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any method and procedures for preparation of each type of solution. Furthermore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.
- Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product
 manufacturer which is used in the manufacturing of batches of drug product, since you have submitted COA of
 multiple irrelevant batches in this section.
- Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis
 of drug substance / pellets along with its standardization record with the primary standard, since you have
 submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from
 that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other
 source of reference standard manufacturing.
- Section 3.2.S.6 specifies that the API manufacturer is using food grade double polyethylene bag for storing these pellets which are highly sensitive to moisture and light. Justification is required in this regard.
- Provide information in section 3.2.S.7.1 amd 3.2.S.7.2 as per CTD guidance document since you have only submitted stability data sheets in section 3.2.S.7 which is not in line with the Form 5-F as well as CTD guidance document
- The stability study of dexlansoprazole pellets performed by Vision Pharmaceuticals specify that the pellets were stored in PET sealed bottles during stability studies while as per section 3.2.S.6 the packaging material of commercially manufactured pellets is food grade double polyethylene bag. Justify how these stability studies are applicable in this case and how it represents the true shelf life of the commercially manufactured pellets.
- Registration Board in its 276th meeting held on 22-25th November, 2017 reviewed the formulation of dexlansoprazole pellets wherein the representative from the pellets manufacturer appeared before the Board and admitted that previously they were not specifying testing of pellets at 5.5 pH in the COA. The submitted stability study data of the three batches of pellets manufactured in 2014 is submitted in which testing at pH 5.5 is also specified. Clarification is required in this regard.
- Submit complete information in section 3.2.P.1 as per form 5F without skipping any section or heading.
- Submit pharmaceutical equivalence report of the applied product along with reference / innovator's product in which all tests as per specifications shall be performed, since you have mentioned that pharmaceutical equivalence is not required and then you have also provided a brief report of dexlansoprazole tablet in which all tests are not performed.

- Provide complete report of comparative dissolution profile along with test parameters, analytical method and how the results are obtained and analysed, since you have only submitted tabulated and graphical representation without specifying any parameter.
- Submit information in section 3.2.P.3 as per the guidance document which specifies that "The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified".
- Provide information in section 3.2.P.3.2 as per the CTD guidance document which specifies that "A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards, since you have only submitted the same table which is already provided in section 3.2.P.1.
- Provide information in section 3.2.P.3.3 as per the CTD guidance document which specifies that "A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified. Proposals for the reprocessing of materials (if any) shall be justified. Any data to support this justification shall be provided in this section. The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified".
- Provide information in section 3.2.P.3.4 as per the CTD guidance document which specifies that "Tests and acceptance criteria shall be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process, to ensure that the process is controlled."
- Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established.
- Provide specifications of the drug product in section 3.2.P.5.1 along with submission of fee for revision of specifications since you have submitted Vision pharmaceuticals specifications of pellets in this section.
- Provide complete and analytical procedures of drug product in section 3.2.P.5.2 since you have provided analytical procedures of pellets in this section. Moreover, in assay test you have mentioned both UV and HPLC test. Clarification is required in this regard.
- Provide validation studies of the analytical method of drug product in section 3.2.P.5.3.
- Provide batch analysis certificate of three batches of drug product in section 3.2.P.5.4 where you have provided COA of dexlansoprazole pellets of Vision Pharmaceuticals with same results and your signatures after removing header containing name of Vision Pharmaceuticals.
- Provide COA of the reference standard / working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard.
- Provide information in section 3.2.P.7 as per the CTD guidance document which specifies that "A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided."
- You have mentioned white to off white pellets in section 3.2.P.1 while white and green pellets in section 3.2.P.8.1. Justification is required in this regard.
- Provide information in section 3.2.P.8.1 and 3.2.P.8.2 as per the Form 5F and CTD guidance document, since you have skipped these two sections and did not provide any information in these sections.
- Justify why only assay and dissolution test at one medium is performed in stability studies as evident from the submitted stability summary sheets.
- Your drug product specifications submitted in section 3.2.P.5.1 and specifications mentioned in COA of stability studies are different specifically in terms of dissolution test. Justify how you have performed stability studies without having any clear written specifications and analytical method.
- Justify the dissolution test in which the acceptance criteria is NLT 75% in 5 hours which is against the specification of innovator's product.
- Justify the dissolution acceptance criteria without specifying the value of Q as well as without identifying the criteria for analysis of results of dissolution test as per the criteria defined in USP general chapter <711> as well as defined by Registration Board in its 293rd meeting.
- Provide complete results of dissolution test including result of individual unit of capsule in the summary sheet or COA since results cannot be analysed without having results of individual units of the capsule.
- Provide stability study data in a proper sequence by providing stability summary sheet of individual batch along with proper separators to provide COA / raw data sheets along with HPLC chromatograms of standard and sample

for the particular time point of that batch. Your submitted data is without any sequence, you have provided all COA and raw data sheets together and the rest of the data is also provided without proper sequence and sperators as per the guidelines of Registration Board. Submit your aligned data in a sequence so that further evaluation may be carried out.

- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
 - o Reference of previous approval of applications with stability study data of the firm (if any)
 - o 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).
 - O Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
 - o Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
 - Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

Decision of 323rd meeting of Registration Board:

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

Response by the firm:

Sr. No	Short coming	Annexure
01	GMP certificate /inspection report of the firm conducted	Firm has not submitted GMP certificate / inspection
	within a period of last three years.	report.
02	Provide Quality Overall Summary in module 2 as per	Firm has not submitted QOS as per WHO template.
	WHO QOS PD template or as per the template defined by	
	Registration Board by providing summarized data in the	
	tabulated form. You have submitted same data of module	
	3 in QOS as well which is not in line with the CTD	
	guidance document.	
03	Submit data in section 3.2.S.4.1 as per the guidance	Firm has submitted copies of the Drug substance
	document approved by Registration Board which specifies	specifications and analytical procedures used for routine
	that "Copies of the Drug substance specifications and	testing of the Drug substance Active Pharmaceutical
	analytical procedures used for routine testing of the Drug	Ingredient by both Drug substance & Drug Product
	substance Active Pharmaceutical Ingredient by both Drug	manufacturer
	substance & Drug Product manufacturer is required."	
04	Provide complete report of verification studies of the	Firm has not submitted report of verification studies of the
	analytical method of drug substance performed by drug	analytical method of drug substance performed by drug
	product manufacturer in section 3.2.S.4.3, since you have	product manufacturer.
	only submitted tabulated results without any procedures	
	for preparation of each type of solution. Furtherore, you	
	have performed 6 replicates in specificity test which is not	
05	in line with the recommendations of ICH.	Firm has submitted COA of batch number DLP664.
05	Provide COA of relevant batch of drug substance from	Firm has submitted COA of batch number DLP004.
	both API manufacturer as well as drug product manufacturer which is used in the manufacturing of	
	batches of drug product, since you have submitted COA	
	of multiple irrelevant batches in this section.	
06	Provide COA of the reference standard / working standard	Firm has not sumitted COA of reference / working
00	in section 3.2.S.5 which is actually used in the analysis of	standard.
	drug substance / pellets along with its standardization	Standard.
	record with the primary standard, since you have	
	submitted COA of batch No WS/RLP/01 from Integrin	
	Life Sciences whose product description is different from	
	that specified in section 3.2.S.1 of your application and is	
	neither the manufacturer of hese pellets or any other	
	source of reference standard manufacturing.	
07	Section 3.2.S.6 specifies that the API food grade double	Three polyethylene bag used for packing of pellets.
	manufacturer is using polyethylene bag for storing these	Two transparent and one black color bags along with silica
	which are pellets highly sensitive to moisture and light.	gel.
	Justification is required in this regard.	
08	Provide information in section 3.2.S.7.1 and 3.2.S.7.2 as	Firm has submitted information in section 3.2.S.7.1 and
	CTD per guidance document since you have only	3.2.S.7.2 as CTD per guidance document.

submitted stability data sheets in section 3.2.S.7 which is

	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
	not in line with the Form 5-F as well as CTD guidance document.	
09	The stability study of Vision Dexlansoprazole pellets performed by Pharmaceuticals specify that the pellets were stored in PET sealed bottles during stability studies while as per section 3.2.S.6 the packaging material of commercially manufactured pellets is food grade double polyethylene bag. Justify how these stability studies are applicable in this case and how it represents the true shelf life of the commercially manufactured pellets.	Study performed at lab scale and in chamber they placed sample in pet bottle and for commercial they provide polythene bags and drum which is not possible in pet bottle.
10	Registration Board in its 276th meeting held on 22-25th November, 2017 reviewed the formulation of Dexlansoprazole pellets wherein the manufacturer appeared before the Board and admitted that previously they were not specifying testing of pellets at 5.5 pH in the COA. The submitted stability study data of the three batches of pellets manufactured in 2014 is submitted in which testing at pH 5.5 is also specified. Clarifications required in this regard.	DMF provided by vision pharma
11	Submit complete information in section 3.2.P.1 as per form 5F without skipping any section or heading.	Submitted by the firm.
12	Submit pharmaceutical equivalence report of the applied product along with reference / innovator's product in which all tests as per specifications shall be performed, since you have mentioned that pharmaceutical equivalence is not required and then you have also provided a brief report of Dexlansoprazole tablet in which all tests are not performed.	Firm has submitted pharmaceutical equivalence studies against the comparator product manufactured by Weatherfolds pharma.
13	Provide complete report of comparative dissolution profile along with test parameters, analytical method and how the results are obtained and analysed, since you have only submitted tabulated and graphical representation without specifying any parameter	Firm has submitted results of comparative dissolution profile against the brand leader.
14	submit information in section 3.2.P.3 as per the guidance document which specifies that The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified"	Firm has submitted information in section 3.2.P.3 as per the guidance document.
15	Provide information in section 3.2.P.3.2 as per the CTD guidance document which specifies that "A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards, since you have only submitted the same table which is already provided in section 3.2.P.1	Firm has submitted information in section 3.2.P.3.2 as per the guidance document.
16	Provide information in section 3.2.P.3.3 as per the CTD guidance document which specifies that "A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified. Proposals for the reprocessing of materials (if any) shall be justified. Any data t supports this justification shall be provided in this section. The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall	Firm has submitted information in section 3.2.P.3.3 as per the guidance document.

	proforably be continuous, any holding time shall be	T
	preferably be continuous; any holding time shall be justified"	
17	Provide information in section 3.2.P.3.4 as per the CTD guidance document which specifies that "Tests and acceptance criteria shall be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process, to ensure that the process is controlled."	Firm has submitted information in section 3.2.P.3.4 as per the guidance document.
18	Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established	Firm has not submitted process validation protocols.
19	Provide specifications of the drug product in section 3.2.P.5.1 along with submission of fee for revision of specifications since you have submitted Vision pharmaceuticals specifications of pellets in this section.	Firm has submitted specifications of the drug product in section 3.2.P.5.1.
20	provide complete and analytical procedures of drug product in section 3.2.P.5.2 since you have provided analytical procedures of pellets in this section. Moreover, in assay test you have mentioned both UV and HPLC test. Clarifications required in this regard	Firm has submitted specifications of the drug product in section 3.2.P.5.2.
21	Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.	Firm has not submitted complete validation studies of the analytical method of drug product in section 3.2. P.5.3.
22	provide batch analysis certificate of three batches of drug product in section 3.2.P.5.4 where you have provided COA of Dexlansoprazole pellets of Vision Pharmaceuticals with same results and your signatures after removing header containing name of Vision Pharmaceuticals.	Firm has submitted Batch analysis report of 3 stability batches.
23	Provide COA of the reference standard I working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard	Firm has not submitted COA of reference standard / working standard.
24	Provide information in section 3.2.P.7 as per the CTD guidance document which specifies that "A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided."	Firm has submitted details of container closure system.
25	You have mentioned white to off white pellets in section 3.2.P.1 while white and green pellets in section 3.2.P.8.1. Justification is required in this regard	Written mistakenly, revised and correct submitted.
26	Provide information in section 3.2.P.8.1 and 3.2.P.8.2 as per the Form 5F and CTD guidance document, since you have skipped these two sections and did not provide any information in these sections.	Firm has submitted information in section 3.2.P.8.1 and 3.2.P.8.2.
27	justify why only assay and dissolution test at one medium is performed in stability studies as evident from the submitted stability summary sheets	Firm has now submitted dissolution test results at different medium in stability studies.
28	Your drug product specifications submitted in section 3.2.P.5.1 and specifications mentioned in COA of stability studies are different specifically in terms of dissolution test. Justify how you have performed stability studies without having any clear written specifications and analytical method.	Firm has submitted specifications and analytical method of drug product.
29	justify the dissolution test in which the acceptance criteria NLT 75% in 5 hours which is against the specifications of innovator's product	Typo mistake Revised COA attached
30	justify the dissolution acceptance criteria without specifying the value of Q as well as without identifying the criteria for analysis of results of dissolution test as per the criteria defined in USP general chapter as well as defined by Registration Board in its 293d meeting	Corrected and resubmitted by the firm

21	annelle complete months of discolution (c) (1 1)	Davided COA are submitted by the firm
31	provide complete results of dissolution test including	Revised COA are submitted by the firm.
	result of individual unit of capsule in the summary sheet	
	or COA since results cannot be analysed without having	
	results of individual units of the capsule	
32	provide stability study data in a proper se stability	Firm has submitted stability data in a proper sequence.
	summary sheet of individual batch along with proper	
	separators to provide COA / raw data sheets along with	
	HPLC chromatograms of standard and sample for the	
	particular time point of that batch. Your submitted data is	
	without any sequence, you have provided all COA and	
	raw data sheets together and the rest of the data is also	
	provided without proper sequence and separators as per	
	the guidelines of Registration Board. Submit your aligned	
	data in a sequence so that further evaluation may be	
	carried out	
33	submit stability study data in section 3.2.P.8.3 as per the	Firm has submitted response against the 6 points checklist
	checklist approved by Registration Board in its 296th	as per CTD guidance document.
	meeting and the CTD guidance document, which includes	
	the following:	
	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 both stability chambers	
	numenty monitoring of bour stability chambers	

Decision: Deferred for following observations:

- Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.
- Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any procedures for preparation of each type of solution. Furtherore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.
- Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other source of reference standard manufacturing.
- Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established
- Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.
- Provide COA of the reference standard I working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard

Firm's response:

Sr.#	Observation	Reply
1.	Provide Quality Overall Summary in module 2 as per WHO	Submitted
	QOS PD template or as per the template defined by	
	Registration Board by providing summarized data in the	
	tabulated form. You have submitted same data of module 3	
	in QOS as well which is not in line with the CTD guidance	
	document	

2.	Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any procedures for preparation of each type of solution. Furtherore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.	Firm has submitted revised analytical method verification studies performed by M/s Wezen Pharmaceuticals.
3.	Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other source of reference standard manufacturing.	Firm has submitted COA of working standard form M/s Vision Pharmaceuticals.
4.	Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established	Firm has submitted revised process validation protocol including the critical steps, sampling plan, and evaluation criteria for the process of capsule filling, sealing and blistering.
5.	Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.	Submitted.
6.	Provide COA of the reference standard in working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard	Firm has submitted COA of working standard form M/s Vision Pharmaceuticals.

Decision: Deferred for submission of Pharmaceutical equivalence and Comparative Dissolution Profile (CDP) studies against the innovator's product.

268.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☑ Manufacturer☐ Importer☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	Status of application	☑ New Drug Product (NDP)☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	□ Domestic sale□ Export sale⊠ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24364: 03-09-2021
	Details of fee submitted	PKR 50,000/-: 05-01-2021
	The proposed proprietary name / brand name	NEXIDORE 250mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Doripenem Monohydrate Eq. to Doripenem250mg

Pharmaceutical form of applied drug	Glass vial filled with white to slightly yellowish, o white crystalline powder.
Pharmacotherapeutic Group of (API)	Carbapenem
Reference to Finished product specifications	In house
Proposed Pack size	1's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Finibax Intravenous Infusion 0.25g (PMDA Japa Approved)
For generic drugs (me-too status)	NA
Name and address of API manufacturer.	KOPRAN RESEARCH LABORATORIES LIMITE K4/4, Additional MIDC, At & Post Birwadi, Taluk Mahad, District Raigad - 402 302 Maharashtra, INDIA
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templated firm has summarized information related nomenclature, structure, general properties, solubilities physical form, manufacturers, description manufacturing process and controls, impurities specifications, analytical procedures and its validation batch analysis and justification of specification reference standard, container closure system and stabilities of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed data for both drug substand data related to nomenclature, structure, gener properties, solubilities, physical form, manufacturer description of manufacturing process and control impurities, specifications, analytical procedures and invalidation, batch analysis and justification specification, reference standard, container closur system and stability studies of drug substance. Firm has not submitted verification studies analytical method for the testing of drug 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 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:	Firm has submitted data of drug product including description, composition, pharmaceutical development manufacture, manufacturing process and procedurely, process validation protocols, control excipients, control of drug product, specification analytical procedures, validation of analytical procedures, batch analysis, justification specifications, reference standard or materials, contain closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Not performed by the firm
A = 1-4:-1 = 1 = -1: 1-4:	Firm has submitted report of validation of analytic
Analytical method validation/verification of product	method for the drug product.

		At & Post Birwadi, T	aluka Mahad, District Rai	gad - 402 302 Maharashtra, INDIA	
API	Lot No.	DIPV/B2002002, DPIV/P2001003, DPIV/P2001004			
	cription of Pack ntainer closure system)	Glass vial			
Stab	oility 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 Period	Real time: 6 months Accelerated: 6 month	s		
Freq	quency	Accelerated: 0, 3, 6 (Maccelerated: 0, 3, 6 (-		
Bato	ch No.	DN-001	DN-002	DN-003	
Bato	ch Size	1200 vials	1200 vials	1200 vials	
Man	nufacturing Date	04-2020	04-2020	04-2020	
Date	e of Initiation	25-04-2020	25-04-2020	25-04-2020	
No.	of Batches		03		
	DOCUMENTS / DA	TA TO BE PROVIDE	D ALONG WITH STA	BILITY STUDY DATA	
1.	Reference of previous approximately study data of the		th Not applicable.		
2.	Approval of API/ DML/GMP certificate of API Firm has submitted copy of GMF manufacturer issued by concerned regulatory KD/89275/2020/11/33788) issued by				
3.	Documents for the proapproval from DRAP (in		drugs for clinical tr for import of Dor Research Laborato MIDC, At & Post Raigad - 402 302 M (I&E) DRAP field o 04-2020. • Firm has submitted of dated 08-04-2020 sp	copy of Form 6 "License to importial, examination, test or analysis" ripenem 3Kg from M/s Kopranories Limited K4/4, Additional Birwadi, Taluka Mahad, District Maharashtra, INDIA issued by AD ffice. The license was issued on 08-copy of commercial invoice cleared becifying import of 3Kg doripenem PV/B2002002, DPIV/P2001003,	
4.	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 Haudit trail reports on prod		Firm has submitted audit trail record of product testing of HPLC for two day 24-04-2020 and 25-04-2020.		
6.	1 1		al temperature and hum		
Eva	luation by PEC:				
Qn	No Shortcomings comm	unicated	Response by the fir	rm	
1.	Submit differential fe product, since the not SRO No. F.7-11/2012 7th May 2021 while to	e for the registration of apification for revision of fee 2-B&A/DRA was publishing application was received on 3 rd September 2021.	plied e vide ed on		

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2.	Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-	Module I is submitted as per CTD guidance document.
	sections instead of referring to annexures.	
3.	Justify the finished product specifications as "Inhouse specifications" since the drug product monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of	Product specifications are revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated.
	requisite fee.	Revised FPP specifications, method of analysis is submitted.
4.	Justify the use of drug substance having in house specifications while the drug substance specifications are present in JP monograph for "Doripenem hydrate"	Revised specification & method of analysis for Doripenem hydrate as per JP is submitted.
5.	Justify the limit of water from $4.0-5.5\%$ in drug substance specifications, while JP monograph specifies the limit from $4.0-5.0\%$.	Drug substance was analyzed using a manufacturer specs and method of analysis at time of development. Moreover, in water contents of drug substance also qualifies the acceptance limit of JP.
6.	Justify why the test for residue on ignition is not performed for the drug substance since it is recommended in JP monograph.	Drug substance was analyzed using a manufacturer specs and method of analysis at time of development where residue on ignition wasn't part of specifications. Now revised specs is submitted.
7.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Specifications & method of analyses from Drug Substance & Drug Product manufacturers is submitted.
8.	Justify the use of a different analytical method for assay testing of drug substance from that specified in JP monograph. The method of drug substance manufacturer is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and	Drug substance was analyzed by using manufacturer's method of analysis at time of development that is why testing conditions differs from that of JP monograph. Product specifications are revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Revised drug substance specification & method of
9.	the formula for calculation of results of assay. Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.	analysis as per JP is submitted. At time to development we followed in-house method of analysis and submitted analytical method validation. We started following the JP at 12 months' study time-point. Now the Analytical Method Verification Protocol & Report is submitted.
10.	Justify how 260mg of Doripenem Monohydrate eq.to Doripenem is equivalent to 250mg of doripenem as per the label claim.	Molecular weight of Doripenem Monohydrate = 438.52 Molecular weight of Doripenem = 420.50 Factor = 438.52 / 420.50 = 1.04 Equivalent weight of Doripenem monohydrate for 250mgDoripenem = 250 x 1.04 = 260mg
11.	Justify how the applied drug is to be supplied with 10ml of sodium chloride 0.9% solution, since the innovator product recommends different volume for reconstitution.	10ml of sodium chloride 0.9% solution is for primary reconstitution which will then be further diluted as per requirements.
12.	Justify why pharmaceutical equivalence studies are not performed.	As Nexidore 250mg injection is ready to fill product, and fill weight of 250mg injection is half of 500mg injection. There is no addition of any other contents in the

		formulation so pharmaceutical equivalence study has been done against dorinem 500mg injection by ICI Pakistan.
13.	The process validation protocols does not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard.	Revised prospective process validation protocol is submitted.
14.	Justify the drug product specifications section (3.2.P.5.1) with water contents from 4.0% to 5.5% while the JP monograph for the drug product specifies water contents to be 4.0 to 5.0%.	Product specifications has been revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Moreover during stability study the water contents results also complies the JP limits(4-5%)
15.	Justify the limit of assay from $90-115\%$ since the JP monograph specifies the assay limit from $95-105\%$.	Product specifications has been revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Moreover during stability study the Nexidore assay results also complies the JP limits(95-105%).
16.	Justify the use of a different analytical method for assay testing of drug product from that specified in JP monograph. The analytical method of drug product is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, total run time and retention time, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay.	Drug substance was analyzed by using manufacturer's method of analysis at time of development that is why testing conditions differs from that of JP monograph. Product specifications are revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Revised specification & method of analysis for drug product as per JP is submitted.
	results of assay.	
17.	Justify the assay preparation step in the assay testing of drug product specifications in which the contents of only 1 vial is taken, justify how the contents taken from only 1 vial can be considered representative of the whole batch.	No justification is provided by the firm.
17.	of drug product specifications in which the contents of only 1 vial is taken, justify how the contents taken	Nexidore Injection is ready to fill product. It doesn't contain inactive ingredients, so there wouldn't need the test of specificity during validation studies. Now we are following JP method and analytical method verification
	of drug product specifications in which the contents of only 1 vial is taken, justify how the contents taken from only 1 vial can be considered representative of the whole batch. Justify why the test of specificity is not performed during the validation studies of the analytical method	Nexidore Injection is ready to fill product. It doesn't contain inactive ingredients, so there wouldn't need the test of specificity during validation studies. Now we are
18.	of drug product specifications in which the contents of only 1 vial is taken, justify how the contents taken from only 1 vial can be considered representative of the whole batch. Justify why the test of specificity is not performed during the validation studies of the analytical method of drug product. Provide details of the concentration in mg/ml of different solutions i.e. 50% to 150% used in accuracy	Nexidore Injection is ready to fill product. It doesn't contain inactive ingredients, so there wouldn't need the test of specificity during validation studies. Now we are following JP method and analytical method verification study of product is attached with inclusion of specificity. Concentration of 50% solution in mg/ml: 125/100 x 1/50 = 0.025mg/ml Concentration of 100% solution in mg/ml: 250/100 x 1/50 = 0.05mg/ml Concentration of 150% solution in mg/ml: 375/100 x 1/50 = 0.075mg/ml The concentration of standard solution recommended by JP is 0.125mg/ml which is different from the 100%

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		at stability for atleast three months so by the time sterility will come up and if any test fails the results will together come up.
22.	Justify the use of 25ml type-II glass vial for the applied drug product since as per your submission the drug product is to be reconstituted in 10ml normal saline.	It was typo error at time of submission. It is 15mL Type I glass vial.
23.	Justify how the results of initial time point is different at real time and accelerated stability data sheet for batch DN-001 and DN-002.	The product has been tested separately for real time and accelerated time stability that's why their results vary but it is in acceptable range.
24.	Justify how the results of pH and assay of batch DN-001 and DN-002 at initial time point in real time stability studies is exactly same.	It is typo error
25.	You have submitted that all stability batches were manufactured using the drug substance batch No. DPIV/P2001003. For manufacturing of 3 batches each having batch size 1200 vials, approximately 1.87Kg drug substance is required, while as per the clearance documents and commercial invoice 1Kg drug substance of batch number DPIV/P2001003 was imported. Justify how three batches were manufactured using the drug substance having batch number DPIV/P2001003.	Three stability batches were manufactured with 312gm of powder from each of 3 containers. Consumption detail of each API lots for manufacturing of three stability batches are: Nexidore 250mg Injection (DN-001): DPIV/B2002002 Nexidore 250mg Injection (DN-002): DPIV/P2001003 Nexidore 250mg Injection (DN-003): DPIV/P2001004 Firm has not submitted documents for import of these lots of API.
26.	Justify why stability testing was not performed for the drug product at the end of accelerated stability study.	We have already submitted complete accelerated stability study data (6 months). However, attaching again herewith for your review in Annexure 13.we are also providing 9th, 12th, 18th stability study data as per JP method.
27.	Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.	Submitted by the firm.

Decision of 323rd meeting of Registration Board:

Registration Board after thorough deliberation observed that the firm has not developed the product as per specifications laid down in Japanese Pharmacopoeia. The Board therefore decided not to accept the stability study data and advised the applicant to again perform product development and stability studies of three batches and submit the data on Form 5-F as per the relevant guidance document.

Submission by the firm:

Firm has submitted revised data in which testing has been performed as per JP monograph. The details of revised data is as under:

data is as under.	
REVISED DA	ATA SUBMITED BY THE FIRM
Name and address of API manufacturer.	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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

			of specification, reference standard, and stability studies of drug
(Conditions & duration of Stability studies)		substance at both accelera The accelerated stability of 75% ± 5% RH for 6 mon	ty study data of 3 batches of drug ted as well as real time conditions. data is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / ths. The real time stability data is 65% \pm 5% RH for 48 months.
		description, composition manufacture, manufacture process validation protoco drug product, specific validation of analytica	l procedures, batch analysis, cations, reference standard or
Pharmaceutical Equi Dissolution Profile	valence and Comparative	Pharmaceutical equivaler Dorinem Injection 250mg	nce studies are performed with
Analytical method vali	dation/verification of product	Firm has submitted report for the drug product.	of validation of analytical method
	STABILIT	TY STUDY DATA	
Manufacturer of API			MITED K4/4, Additional MIDC, gad - 402 302 Maharashtra, INDIA
API Lot No.	DIPV/B22010005 DIPV/B22010006 DIPV/B22010007		
Description of Pack (Container closure syst	Glass vial		
Stability Storage Cond		°C / 65% ± 5%RH 2°C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 mont		
Frequency	Accelerated: 0, 3, 6 Real Time: 0, 3, 6 (1)		
Batch No.	DN22-001	DN22-002	DN22-003
Batch Size	900 vials	900 vials	900 vials
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	21-09-2022	21-09-2022	21-09-2022
No. of Batches		03	
DOCUMEN	TS / DATA TO BE PROVID	ED ALONG WITH STAI	BILITY STUDY DATA
	vious approval of applications v ta of the firm (if any)	with Meropenem 500mg &	1g Injection (M-296)
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 (KD/89275/2020/11/33788) issued by FDA Mahrasi dated 20-10-2020. The certificate is valid till 19-10-20			788) issued by FDA Mahrashtra
3. Documents for the procurement of API wapproval from DRAP (in case of import).		drugs for clinical tr for import of Dor Research Laborato	copy of Form 6 "License to importial, examination, test or analysis" ipenem 3Kg from M/s Kopranries Limited K4/4, Additional Birwadi, Taluka Mahad, District

Raigad - 402 302 Maharashtra, INDIA issued by AD (I&E) DRAP field office. The license was issued on 05-09-2022. Firm has submitted copy of commercial invoice cleared dated 05-09-2022 specifying import of 6Kg Doripenem Batch No. DPIV/P22010005, DPIV/P22010006, DPIV/P22010007. Data of stability batches will be supported by Firm has submitted complete record of testing of all attested respective documents like chromatograms, batches along with chromatograms, raw data sheets, Raw data sheets, COA, summary data sheets etc. COA and summary data sheets. Compliance Record of HPLC software 21CFR & Firm has submitted audit trail record of product testing of 5. audit trail reports on product testing HPLC for two days. 6. 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 humidity monitoring of stability chambers (real time and accelerated) accelerated stability chambers.

Evaluation by PEC:

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

269.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☑ Manufacturer☐ Importer
		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	 □ Domestic sale □ Export sale ☑ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7850: 10-03-2021
	Details of fee submitted	PKR 20,000/-: 05-01-2021
	Proposed proprietary name / brand name	NEXIDORE 500mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	
	Pharmaceutical form of applied drug	Glass vial filled with white to slightly yellowish, off white crystalline powder.
	Pharmacotherapeutic Group of (API)	Carbapenem

	Reference to Final specifications	ished product	In house
	Proposed Pack size		1's
			As per SRO
	status in reference regul	atory authorities	Finibax Intravenous Infusion 0.5g (PMDA Japan Approved)
	For generic drugs (me-to-		Dorinem Injection 500mg by ICI Pakistan Ltd.
	Name and address of API manufacturer.		KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA
	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 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 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.
			Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control 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 the comparator i.e. Dorinem 500mg injection of ICI Pakistan Ltd Batch No. 0E458 Mfg date 05-2020.
			Firm has submitted report of validation of analytical method for the drug product.
	STAB		ILITY STUDY DATA
Manuf	acturer of API		CARCH LABORATORIES LIMITED K4/4, Additional MIDC, At Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA
API Lo	ot No.	DIPV/B2002002 DPIV/P2001003 DPIV/P2001004	,
	ption of Pack iner closure system)	Glass vial	

Accelerated: 40°C ± 2°C / 75% ± 5%RH	Stabil	lity Storage Condition	Paul time : 30°C	+ 2°C /	65% + 5% DH		
Accelerated: 6 months	Smorthly 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: 0, 3, 6 (Months)							
Batch Size 1200 vials 350 vials 350 vials Manufacturing Date 04-2020 04-2020 04-2020 04-2020 Date of Initiation 27-04-2020 27-04-2020 27-04-2020 No. of Batches 03 03 05 05 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) 05 04 05 05 05 05 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). 10 05 05 05 05 05 05 05	Frequ	iency			-		
Manufacturing Date O4-2020 O4-2020 O4-2020 O4-2020 O7-04-2020 O7-04-2	Batch	ı No.	DN-004	DN-00	5	DN-006	
Date of Initiation 27-04-2020 27-04-2020 27-04-2020 27-04-2020 No. of Batches 03 DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA 1. Reference of previous approval of applications with stability study data of the firm (if any) 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) Evaluation by PEC: Shortcomings communicated Evaluation by PEC: Shortcomings communicated Evaluation by PEC: Shortcomings communicated Response by the firm Firm has revised the specifications as "Inhouse specifications along with submission of requisite fee." Terevised method is still different from JP monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee.	Batch	Size	1200 vials	350 via	ıls	350 vials	
No. of Batches DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	Manu	facturing Date	04-2020	04-202	0	04-2020	
DOCUMENTS / DATA 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). 5. Firm has submitted copy of GMP certificate clinical trial, examination, test or analysis" for import, and the submitted copy of commercial invoice cleared on the supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. 6. Compliance Record of HPLC software 21CFR & audit trail reports on product testing of stability chambers (real time and accelerated) 6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) 7. Evaluation by PEC: Shortcomings communicated Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9, since the submitted reference is of Doribex Injection of Janssen cilag international N.V Belgium is currently withdrawn by EMA. Justify the finished product specifications as "Inhouse specifications along with submission of requisite fee. Pirm has submitted evidence of approval in PMDA Japin App in the revised method is still different from JP monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee.	Date	of Initiation	27-04-2020	27-04-2	2020	27-04-2020	
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). 5. Firm has submitted copy of Form 6 "License to import drow the firm Doripenem 3Kg from M/s Kopran Research Labou Limited K4/4, Additional MIDC, At & Post Birwadi, Mahad, District Raigad - 402 302 Maharashtra, INDIA by AD (I&E) DRAP field office. The license was issued 04-2020. 6. Firm has submitted copy of commercial invoice cleared 08-04-2020, specifying import of 3Kg doripenem Bat DIPV/B2002002, DPIV/P2001003, DPIV/P2001004. 7. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. 7. Compliance Record of HPLC software Eirm has submitted audit trail record of product testing of stability chambers (real time and accelerated) 8. Compliance Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) 8. Response by the firm 8. Pirm has submitted evidence of approval in PMDA Iag Finibax Intravenous Infusion 0.5 (PMDA Japan App 1 in available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee.	No. o	f Batches	03				
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) Evaluation by PEC: Shortcomings communicated Response by the firm	DOC	UMENTS / DATA TO	BE PROVIDED A	ALONG	WITH STABILIT	TY STUDY DATA	
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 Form 6 "License to import defined trial, examination, test or analysis" for import defined trial, examination, test or analysis" for import defined trial, examination, test or analysis of import). **API CLED DRAP field office. The license was issued 04-2020. **Firm has submitted copy of commercial invoice cleared 08-04-2020 specifying import of 3Kg doripenem Bat DIPV/B2002002, DPIV/P2001003, DPIV/P2001004. **API 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) **6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) **8. **Evaluation by PEC:** **Shortcomings communicated** **Shortcomings communicated** **Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9, since the submitted reference is of Doribex Injection of Janssen citag international N.V Belgium is currently withdrawn by EMA. Justify the finished product specifications as "Inhouse specifications" since the drug product monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee. **Firm has submitted copy of Form 6 "License to impoly of limited in proport of Inject of Time has submitted copy of commercial invoice cleared of the firm has submitted copy of commercial invoice cleared of the post part of 3Kg doripeme Bat DIPV/B2002002, DPIV/P2001003, DPIV/P2001004. **Firm has submitted copy of Form 6 "License to import of 3Kg doripeme Bat DIPV/B2002002, DPIV/P2001003, DPIV/P2001	1.	applications with stabi			plicable.		
with approval from DRAP (in case of import). Clinical trial, examination, test or analysis" for import import). Clinical trial, examination, test or analysis" for import import). Clinical trial, examination, test or analysis" for import import import in the post import of the post import	2.	of API manufacturer is	sued by concerned	KD/892	275/2020/11/33788) issued by FDA Mahrashtra dated 20-	
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: Shortcomings communicated Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9, since the submitted reference is of Doribex Injection of Janssen cilag international N.V Belgium is currently withdrawn by EMA. Justify the finished product specifications as "Inhouse specifications" since the drug product monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee. with chromatograms, raw data sheets, COA and summa sheets. Firm has submitted audit trail record of product testing of for partial testing. Firm has submitted record of digital data logger for temp and humidity monitoring of real time and accelerated submitted record of digital data logger for temp and humidity monitoring of real time and accelerated submitted record of digital data logger for temp and humidity monitoring of real time and accelerated submitted record of digital data logger for temp and humidity monitoring of real time and accelerated submitted record of digital data logger for temp and humidity monitoring of real time and accelerated submitted record of digital data logger for temp and humidity monitoring of real time and submitted record of digital data logger for temp and humidity monitoring of real time and submitted record of digital data logger for temp and humidity monitoring of real time and submitted record of digital data logger for temp and humidity monitoring of real time and submitted record of digital data logger for temp and humidity monitoring of real time and submitted record of digital data logger for temp and humidity monitoring of real time and submitted record of digital da	with approval from DRAP (in case of		clinic Dori Limi Mah by A 04-2 • Firm 08-0	cal trial, examinat penem 3Kg from ted K4/4, Addition ad, District Raigad D (I&E) DRAP fiel 020. has submitted cop 4-2020 specifying	ion, test or analysis" for import of M/s Kopran Research Laboratories all MIDC, At & Post Birwadi, Taluka - 402 302 Maharashtra, INDIA issued doffice. The license was issued on 08-y of commercial invoice cleared dated import of 3Kg doripenem Batch No.		
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: Shortcomings communicated Response by the firm	4.	supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets		with cl sheets.			
temperature and humidity monitoring of stability chambers (real time and accelerated schambers. Evaluation by PEC: Shortcomings communicated Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9, since the submitted reference is of Doribex Injection of Janssen cilag international N.V Belgium is currently withdrawn by EMA. Justify the finished product specifications as "Inhouse specifications" since the drug product monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee. Test of purity as recommended by JP monograph and humidity monitoring of real time and accelerated schambers. Response by the firm Firm has submitted evidence of approval in PMDA Japan App Firm has revised the specification as per JP monograph also submitted fee PKR 7500 for change in specification available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee. Test of purity as recommended by JP monograph	5.	21CFR & audit trail r				trail record of product testing of HPLC	
Shortcomings communicated Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9, since the submitted reference is of Doribex Injection of Janssen cilag international N.V Belgium is currently withdrawn by EMA. Justify the finished product specifications as "Inhouse specifications" since the drug product monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee. Response by the firm Firm has submitted evidence of approval in PMDA Japan App Finibax Intravenous Infusion 0.5g (PMDA Japan App Firm has revised the specification as per JP monograph also submitted fee PKR 7500 for change in specification following terms • Test of purity as recommended by JP monograph	temperature and humidity monitoring of stability chambers (real time and accelerated)		and hu	midity monitoring			
Submit evidence of approval of applied formulation in reference regulatory authorities in section 1.5.9, since the submitted reference is of Doribex Injection of Janssen cilag international N.V Belgium is currently withdrawn by EMA. Justify the finished product specifications as "Inhouse specifications" since the drug product monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee. Firm has submitted evidence of approval in PMDA Japan App Finibax Intravenous Infusion 0.5g (PMDA Japan App Finibax Intravenous Infusion 0.5g (PMDA Japan App Firm has revised the specification as per JP monograph also submitted fee PKR 7500 for change in specification following terms • Test of purity as recommended by JP monograph		-			Th 1 . 1 1		
specifications" since the drug product monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee. also submitted fee PKR 7500 for change in specification. The revised method is still different from JP monograph following terms • Test of purity as recommended by JP monograph	Subr refer subn inter	nit evidence of approval ence regulatory authorities nitted reference is of Doribo national N.V Belgium is cu	in section 1.5.9, si ex Injection of Jansso rrently withdrawn by	nce the en cilag EMA.	Firm has submitted Finibax Intravenous	evidence of approval in PMDA Japan s Infusion 0.5g (PMDA Japan Approved)	
added by the firm	speci	specifications" since the drug product monogravailable in Japanese Pharmacopoeia. Revise		raph is e your	also submitted fee F The revised method following terms • Test of purity a	PKR 7500 for change in specifications. d is still different from JP monograph in s recommended by JP monograph is not	

Mobile phase A and B is used by the firm with run time upto 55 minutes while JP monograph recommends only one typ of mobile phase.

Plant rate set by the firm is Im/minute while JP.

• Flow rate set by the firm is 1ml/minute while JP monograph recommends "Adjust so that the retention time of doripenem is about 15 minutes"

• System suitability requirements are not provided in the specifications of the firm while it is mentioned in JP monograph.

During evaluation of already submitted data by the firm it was identified that firm has used 5 standard chromatograms while JP recommends 6 standards further the JP recommends that theoretical plates should be less than 5000 while the theoretical plates in the submitted data is way above 5000. Further JP monograph recommends a retention time of 15 minutes, while the retention time in firm's data was around 10 minutes.

Justify the use of drug substance having in house specifications while the drug substance specifications are present in JP monograph for "Doripenem hydrate"

Firm has revised the specification as per JP monograph The revised method is still different from JP monograph in following terms

• Test of purity as recommended by JP monograph is not added by the firm

 Mobile phase A and B is used by the firm with run time upto 55 minutes while JP monograph recommends only one typ of mobile phase.

• Flow rate set by the firm is 1ml/minute while JP monograph recommends "Adjust so that the retention time of doripenem is about 15 minutes"

 System suitability requirements are not provided in the specifications of the firm while it is mentioned in JP monograph.

During evaluation of already submitted data by the firm it was identified that firm has used 5 standard chromatograms while JP recommends 6 standards further the JP recommends that theoretical plates should be less than 5000 while the theoretical plates in the submitted data is way above 5000. Further JP monograph recommends a retention time of 15 minutes, while the retention time in firm's data was around 10 minutes.

Further. the analytical method of the drug substance manufacturer is different from JP monograph in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay.

Justify the limit of water from 4.0-5.5% in drug substance specifications, while JP monograph specifies the limit from 4.0-5.0%.

Firm has submitted revised specifications in which limit of water has been changed as per JP monograph.

The drug substance specifications still contain the limit of 4 - 5.5%.

Justify why the test for residue on ignition is not performed for the drug substance since it is recommended in JP monograph. Firm has submitted revised specifications in which residue of ignition has been added as per JP monograph. The drug substance specifications still does not contain this test.

Firm has submitted that they have analysed the drug substance

Justify the use of a different analytical method for assay testing of drug substance from that specified in JP monograph. The method of drug substance manufacturer is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability

by using the method of analysis of drug substance manufacturer at the time of development that's why the testing conditions differ from JP monograph.

Now, the firm has revised the drug substance specifications as per JP monograph but the revised specifications are not exactly as per JP monograph.

	1		
requirements and acceptance criteria and the formula for calculation of results of assay.			
Submit data in section 3.2.S.4.3 as per the decision of 293 rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.	and drug product is studies on drug prosubstance as well. However, the valid method which is emonograph in term temperature, mobilities, standard prefestandard solution, concentration of	s same therefore voluct and consider and consider and consider are partiely different from the sof HPLC columniate phase, UV determined and sample preparation acceptance criter oduction acceptance consider acceptance acce	nethod of drug substance we performed validation red it validated for drug performed on analytical rom that specified in JP in specifications, column tector wavelength, flow and final concentration of tion method and final on, system suitability in and the formula for
Justify how the applied drug is to be supplied with 10ml of sodium chloride 0.9% solution, since the innovator product recommends different volume for reconstitution.	Firm has submitted primary reconstitute requirement.	that 10ml of norr tion which will b	nal saline solution is for e further diluted as per ce product is as follows:
	Date of initial	25-07-2005	12-10-2007
	approval	23-01 - 2003	12-10-2007
	Brand name	Finibax	Doribax
	Current status	Marketed	Discontinued
	Reconstitution	contents of 1	Constitute the 500
		bottle and 1 kit	mg vial with 10 mL
		dissolved in	of sterile water for
		100 mL of	injection or 0.9% sodium
		physiological saline.	chloride injection
		not contain a bac	cteriostatic preservative. d in preparation of the
The process validation protocols does not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard.	in which vial wash sterilization time a However, the firr temperature and ti	ing and sterilization nd temperature is n n has directly se me without provid	sess validation protocols in time as well as dry heat mentioned. Elected the sterilization ing any protocol how to sterilization time and
Justify the drug product specifications section (3.2.P.5.1) with water contents from 4.0% to 5.5% while the JP monograph for the drug product specifies water contents to be 4.0 to 5.0%.		l revised sections a	s per JP monograph
Justify the limit of assay from 90 – 120% since the JP	Firm has submitted	l revised sections a	s per JP monograph
monograph specifies the assay limit from 95 – 105%. Justify the use of a different analytical method for assay testing of drug product from that specified in JP monograph. The analytical method of drug product is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, total run time and retention time, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay.	by using the m manufacturer at t testing conditions of Now the firm has r per JP monograph exactly as per JP m	nethod of analys the time of develor differ from JP mon evised the drug sult the revised nonograph.	bstance specifications as specifications are not
Justify why the test of specificity is not performed during the validation studies of the analytical method of drug product.	any inactive ingred of specificity durin	lient so there would g the validation st	
Justify why the test of water contents and uniformity of dosage units is not performed in the batch analysis stage.	Firm has submitted	i that both tests hav	ve been performed now
Justify the release of drug product batches on 27-04-2020 after performing test of sterility, since the drug substance was	Firm has not subm	itted any justificati	on.

released after testing on 24-04-2020. Justify how the three Firm has only submitted sterility test reports but no batches were manufactured and stability studies were being justification is provided. performed within 3 days only. Justify the use of 25ml type-II glass vial for the applied drug It was a typo error the actual vials are 15 ml type I glass vial. product since as per your submission the drug product is to be reconstituted in 10ml normal saline. Justify the date of initiation of stability studies of 25-4-2020, It was a typo error the actual date of placement in chamber since batches were released on 27-4-2020. was 27-04-2020. You have submitted that all stability batches were Firm has submitted that we used 3 different lots of API for manufactured using the drug substance batch No. manufacturing of 3 batches. It was typo error at time of dossier DPIV/P2001003. For manufacturing of 3 batches each submission. Firm has submitted revised stability data sheets having batch size 1200 vials, approximately 1.87Kg drug for all batches. substance is required, while as per the clearance documents The newly submitted data sheets are different from previously and commercial invoice 1Kg drug substance of batch submitted data sheets in following aspects. number DPIV/P2001003 was imported. Justify how three **Particulars Previously Newly submitted** submitted batches were manufactured using the drug substance having batch number DPIV/P2001003. Batch No DN-004 0 month date 25.04.2020 27.04.2020 3rd month date 25.07.2020 28.07.2020 6th month date 26.10.2020 27.10.2020 API lot # DPIV/P2001003 DPIV/B2002002 Batch No DN-005 0 month date 25.04.2020 27.04.2020 3rd month date 25.07.2020 28.07.2020 6th month date 27.10.2020 26.10.2020 DPIV/P2001003 API lot # DPIV/P2001003 Batch No DN-006 0 month date 25.04.2020 27.04.2020 3rd month date 25.07.2020 28.07.2020 6th month date 26.10.2020 27.10.2020 API lot# DPIV/P2001003 DPIV/P2001004 Firm has also changed the date of testing of 3rd and 6 months • The sterility test and particulate matter was not performed at 3rd or 6th month time point during initially submitted data, however in the newly submitted data sheets the results of both of these tests are also mentioned in the data sheets at 3rd as well as 6th month time point. Firm has submitted that we have already submitted complete Justify why sterility testing was not performed for the drug product at the end of accelerated stability study. accelerated stability data for 6 months however again we are attaching for your review. The sterility test and particulate matter was not performed at 3rd or 6th month time point during initially submitted data, however in the newly submitted data sheets the results of both of these tests are also mentioned in the data sheets at 3rd as well as 6th month time point. Firm has submitted that it was submitted along with the Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed dossier. during the study. However, complete audit trail report is not submitted, partial report of testing of only 24-4-2020 and 27-4-2020 is submitted. Justify how three batches were manufactured on 24-04-2020 Firm has submitted that three stability batches were in which the sterilization of vials for all the batches was manufactured on 24-04-2020 with sterilized vials. Vials are performed collectively on 23-04-2020. Justify how having a sterilized separately for each batch as these was loaded in single step of sterilization of vials for 3 batches can satisfy sterilizer within a separate box, which are labelled for each the definition of a batch. batch. Firm has not submitted any scientific justification for carrying out sterilization of vials collectively for all the three batches. After filling, reconciliation was done for batch consumption The submitted BMR's does not contain any step after the rejection and yields in BMRs while analytical and filling of vials justify how the batches were released after the microbiological reports were separately prepared and filling of vials including details of physical, analytical and incorporated in stability files. microbiological tests.

As per the submitted BMR's 624g of drug substance was filled in each batch while the import documents specify that 3 containers each having 1Kg drug substance was imported.

Justify how three batches were manufactured.

DN-004:

DPIV/B2002002

DN-005:

DPIV/P2001003

DN-006:

DPIV/P2001004

Decision of 313th meeting of Registration Board:

Deferred for following submissions:

- Scientific justification for having drug product specification which is significantly different in terms of test of purity, mobile phase, flow rate / retention time, system suitability requirements, number of injections of the standard solution and theoretical plates from that specified in JP monograph.
- Scientific justification for the analysis of the drug product throughout the stability studies with theoretical plates above 5000, while JP monograph recommends that theoretical plates should be less than 5000.
- Scientific justification for using drug substance having in-house specifications (having completely different analytical method from that recommended in JP monograph) to develop a drug product complying JP pharmacopeia.
- Scientific justification for having limit of water contents from 4.0 5.0% while the water contents specified in the drug substance specifications is 4.0 5.5%.
- Scientific justification for using a drug substance without any test of residue on ignition, while the same test is recommended in the drug product.
- Justify the performance of verification studies of the drug substance using an analytical procedure which is entirely different from that specified in JP monograph.
- Justify the use of 10ml of 0.9% sodium chloride as diluent, since both USFDA as well as PMDA approved reference products recommends different diluent.
- Justify process validation protocls without defining procedure for validation of sterilization cycle.
- Justify analytical method verification studies of drug product without performing test of specificity.
- Justify the release of drug product batches on 27-04-2020 after performing test of sterility, since the drug substance was released after testing on 24-04-2020. Justify how the three batches were manufactured and stability studies were being performed within 3 days only.
- Justification for re-submission of stability data sheets having different dates for testing at 0, 3rd and 6th month time point and test of sterility and particulate matter for all the batches from that specified in initially submitted stability data sheet.
- Submission of complete audit trail report for all tests performed throughout the stability studies.
- Scientific justification for carrying out sterilization of vials collectively for all the three batches.

Submission by the firm:

Firm has submitted revised data in which testing has been performed as per JP monograph. The details of revised data is as under:

data is as direct.	
REVISED DAT	A SUBMITED BY THE FIRM
Name and address of API manufacturer.	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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

Diss	maceutical Equivalence olution Profile lytical method validation/v	and Comparative	Dorinem Injection 500mg	ce studies are performed against
		CTADII IT	Y STUDY DATA	
Mon	ufacturer of API	1		MITED KA/A Additional MIDC
Ivian	uracturer of AFT		CH LABORATORIES LIMITED K4/4, Additional MIDC, Faluka Mahad, District Raigad - 402 302 Maharashtra, INDIA	
API	Lot No.	DIPV/B22010005, DIPV/B22010006, DIPV/B22010007		
	cription of Pack ntainer closure system)	Glass 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 month	hs	
Freq	uency	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (N		
Batc	h No.	DN22-004	DN22-005	DN22-006
Batc	h Size	1000 vials	1000 vials	1000 vials
Man	ufacturing Date	09-2022	09-2022	09-2022
Date	of Initiation	27-09-2022	27-09-2022	27-09-2022
No.	of Batches		03	
	DOCUMENTS / DA	TA TO BE PROVIDI	ED ALONG WITH STAI	BILITY STUDY DATA
1. Reference of previous approval of applications we stability study data of the firm (if any)		with Meropenen Injection 500mg & 1g (M-296)		
2.	2. Approval of API/ DML/GMP certificate of A		API Firm has submitted copy of GMP certificate (No. ory KD/89275/2020/11/33788) issued by FDA Mahrashtra dated 20-10-2020. The certificate is valid till 19-10-2023.	
3.				copy of Form 6 "License to import ial, examination, test or analysis"

		Research Laboratories Limited K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA issued by AD (I&E) DRAP field office. The license was issued on 05-09-2022. • Firm has submitted copy of commercial invoice cleared dated 05-09-2022 specifying import of 6Kg Doripenem Batch No. DPIV/P22010005, DPIV/P22010006, DPIV/P22010007.
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 record of product testing of HPLC for two days
6.		Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

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

270.	Name, address of Applicant / Marketing Authorization Holder	M/s Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	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) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 10-11-2020.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio- Labs dated 21-05-2019 based on the inspection dated 23- 04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio- Labs dated 21-05-2019 based on the inspection dated 23- 04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral 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. 17791: 25-06-2021
Details of fee submitted	PKR 50,000/-: 09-04-2021
The proposed proprietary name / brand name	VARICEF 100mg/5ml Dry Suspension
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate100mg
Pharmaceutical form of applied drug	Almost pink colored powder having strawberry flavor powder for reconstitution
Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
Reference to Finished product specifications	USP
Proposed Pack size	30 ml
Proposed unit price	As per SRO
The status in reference regulatory authorities	Cefixime suspension (USFDA Approved)
For generic drugs (me-too status)	Cefim suspension by Hilton
Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industr Zone, Port Qasim, Karchi.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templar Firm has summarized information related nomenclature, structure, general properties, solubilities physical form, manufacturers, description manufacturing process and controls, impurities specifications, analytical procedures and its validation batch analysis and justification of specification, referent standard, container closure system and stability studies drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed data for drug substance darelated to nomenclature, structure, general properticular solubilities, physical form, manufacturers, description manufacturing process and controls, impuritive specifications, analytical procedures and its validation batch analysis and justification of specification, referent 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 batches drug substance at both accelerated as well as real tinconditions. The accelerated stability data is conducted $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months. The real tinstability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65 \pm 5\%$ F for 24 months.
Module-III Drug Product:	Firm has submitted data of drug product including description, composition, pharmaceutical developme manufacture, manufacturing process and process contributes a validation protocols, control of excipient control of drug product, specifications, analytic procedures, validation of analytical procedures, bat analysis, justification of specifications, referent standard or materials, container closure system a stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivaler for all the quality tests for their product against Cefsp dry suspension.

	Analytical method v	alidation/verification	of Firm has submitted substance and the drug	verification studies of the drug g product.	
	•	STABILIT	Y STUDY DATA		
Manufacturer of API		Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.			
API	Lot No.	18CF10035			
	cription of Pack ntainer closure system)	Glass bottle			
Stab	oility Storage Condition		: 30°C ± 2°C / 65% ± 5%RH ed: 40°C ± 2°C / 75% ± 5%RH		
Tim	e Period	Real time: 6 months Accelerated: 6 months			
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Bato	ch No.	D-006	D-018	D-022	
Bato	ch Size	7500 bottles	7500 bottles	7500 bottles	
Mar	nufacturing Date	01-2019	01-2019	01-2019	
Date	e of Initiation	31-01-2019	31-01-2019	31-01-2019	
No. of Batches		03			
	DOCUMENTS / DA	TA TO BE PROVIDE	D ALONG WITH STAI	BILITY STUDY DATA	
1.	Reference of previous appropriate stability study data of the		th		
2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		ry Additional Director D			
3.	Documents for the pro- approval from DRAP (in c		th		
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 v data sheets, COA and summary		
5.	Compliance Record of H audit trail reports on produ		& NA		
6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real			idity monitoring of real time and		

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit valid contract manufacturing agreement between the contract giver and contract acceptor.
- Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.
- Submit label claim in module 1 as per the reference product along with submission of requisite fee.
- You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in USP. Revise the specifications along with submission of requisite fee.
- The drug substance manufacturer has claimed both BP and USP specifications for the drug substance, provide scientific justification in this regard.

- The drug substance manufacturer has claimed USP specifications for the assay method, while the submitted method is different from USP in terms of column specifications including column length and pore size. Justification is required in this regard.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Submit data in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that "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, since the submitted COA of three batches of API are of 2020 while the drug product batches were manufactured in 2019.
- Justify how your unit formula containing 0.685gm of drug substance is equivalent to 100mg cefixime base per 5ml after reconstitution. Further specify which is the unit which has been taken as reference for your formulation.
- Justify the formulation which is different in terms of qualitative composition from that of innovator product Suprax suspension.
- Innovator product has not used sodium citrate which is used in your formulation as preservative along with sodium benzoate. Justify the use of two different preservatives without determining the preservative effectiveness.
- The acceptance criteria for pH is 2.5 to 4.5 while your compatibility results specifies that after reconstitution with the recommended diluent / solvent, the pH is 5.08 which lies outside the acceptance criteria. Justify how you have passed this formulation and performed stability studies on the same formulation.
- The process validation studies have been conducted on three batches having 5000 bottles batch size. While the batch size of the commercial batches for which stability study data is submitted, ranges from as low as 7500 and as high as 60,000 bottles. Justification is required in this regard.
- Submit detailed method of analysis of the drug product in section 3.2.P.5.2 instead of submitting print of USP monograph.
- Submit exact details of the assay preparation since the words "Reconstitute sample as directed n the labelling" should not be used in the method adopted by a firm. Instead provide details about the exact diluent along with volume in which reconstitution is to be carried out.
- Justify the analytical method verification studies without performing test or specificity and precision. Further also specify the exact concentration of solutions of 50%, 100% and 150% solutions used in the analysis of accuracy and recovery test.
- Provide COA of the reference standard / working standard actually used in the analysis of drug product in section 3.2.P.6.
- You have provided batch release certificate for batch D-220, D-221 and D-222 in section 3.2.P.5.4 while provided stability study data for batch D-006, D-018 and D-022 in section 3.2.P.8.3. Clarification is required in this regard.
- Provide batch size of Batch D-006 in terms of number of bottles instead of providing batch size in terms of Kg.
- You have submitted that API lot used in manufacturing of stability batches is 18CF10035 while submitted COA of totally different batches in section 3.2.S.4.4. Justify why data was not submitted in line with the guidance document issued by Registration Board.
- Justify why only 3 chromatographs of the standard solution was run while USP General chapter <621> recommends that five replicates of standard solution should be used for system suitability studies.
- Provide raw data sheets showing calculation of the results during the stability studies for all batches.
- Justify why the stability study data is section 3.2.P.8.3 is not submitted as per the guidance document issued by Registration Board.

- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
 - o Reference of previous approval of applications with stability study data of the firm (if any)
 - O Documents for the procurement of API with approval from DRAP (in case of import).
 - o Compliance Record of HPLC software 21CFR & audit trail reports on product testing
- Justify why BMR of different batches is submitted than that for which stability studies were conducted.

Decision of 323rd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response by the Firm:

	Deficiencies/ Short-comings	Justifications
1.	Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7 th May 2021 while this application was received R&I section of DRAP after 7 th May 2021.	Firm has submitted the differential fee.
2.	Submit valid contract manufacturing agreement between the contract giver and contract acceptor.	Firm has submitted the valid contract.
3.	Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.	Firm has submitted the Module 1 as per CTD guidance document.
4.	Submit label claim in Module 1 as per the reference product along with submission of requisite fee.	Firm has submitted the label claim as per reference product.
5.	You have mentioned Innovator's Specs in Sec. 1.5.6 in Module 1 while the Drug Product Monograph is available in USP. Revise the Specs. Along with Submission of Requisite Fee.	Firm has explained that Innovator's specs was written mistakenly in Sec 1.5.6. Rest of the dossier is of USP specs already. Corrected Sec 1.5.6 has been attached.
6.	The drug substance manufacturer has claimed both BP and USP specs. For the assay method, while the submitted method is different from USP in terms of column specs including column length and pore size. Justification is required in this regard.	Drug substance manufacturer used to follow both specs. However, they have performed on USP for our product.
7.	The drug substance manufacturer has claimed USP specifications for the Assay method, while the submitted method is different from USP in terms of column specifications including column length and pore size. Justification is required.	Firm has explained that mistake was from the drug substance manufacturer. They have corrected the assay method.
8.	Submit data in sec. 3.2.S.4.1 as per the guidance doc. approved by the reg. board which specifies that "copies of drug substance specs and analytical procedure used for routine testing of API by both drug substance and drug product manufacturer is required.	Firm has submitted copies of drug substance specs and analytical procedure used for routine testing of API by both drug substance and drug product manufacturer.
9.	Submit data in section 3.2.S.4.3 as per the decision of 293 rd meeting of registration board which states that the "analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the drug product manufacturer for both compendial as well as non-drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of analytical method of drug substance.	Firm has submitted analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the drug product manufacturer
10.	Submit data in section 3.2.S.4.4 as per the guidance document approved by registration board which specifies that "provide results analyses of relevant batch(s) of drug substance performed by the drug product manufacturer used during product development and stability studies, along with COA of same batch from API manufacture, since the submitted COA of three batches of API are of 2020 while the drug product batches were manufactured in 2019."	Firm has submitted the results analyses of relevant batch(s) of drug substance performed by the drug product manufacturer used during product development and stability studies, along with COA of same batch from API manufacture.
11.	Justify how your Unit Formula Containing 0.685g of Drug Substance is Eq. to 100mg Cefixime base per 5ml After	Firm has submitted the calculation as per reference formulation.

Reconstituted. Further Specify which is the Unit which has been taken as Reference for your Formulation.	
12. Justify the formulation which is different in terms of qualitative composition from that of innovator product suprax suspension.	Firm has submitted the rationale of using excipients in its formulation.
13. Innovator product has not used sodium citrate which is used in your formulation as preservative along with sodium benzoate. Justify the use of two different preservative without determining preservative effectiveness.	Firm has justify that sodium citrate has been used as buffering agent for pH control, not the preservative.
14. The acceptance criteria for pH is 2.5 to 4.5 while your compatibility results specifies that after reconstitution with the recommended diluent/solvent, the pH is 5.08 which lies outside the acceptance criteria. Justify how you have passed this formulation and performed stability studies on same formulation.	Firm has justify that it was typo error in pH. Revised pharmaceutical development document has been submitted.
15. The process validation studies have been conducted on three batches having 5000 bottles batch size. while the batch size of commercial batches for which stability study data is submitted, ranges from as low as 3000 and as high as 10,000 bottles. Justification is required in this regard.	Firm has explained that batch sizes wasn't harmonized for submitted stability batches but from these new submitted batches we have standardize the batch size onward.
16. Submit detailed method of analysis of drug product in section 3.2.P.5.2 instead of submitting print of USP monograph.	Firm has submitted the detailed method of analysis in 3.2.P.5.2
17. Submit exact details of assay preparation since words "reconstitute sample as directed in the labeling" should not be used in the method adopted by firm instead provide details about the exact diluent along with volume in which reconstituted is to be carried out.	Firm has submitted the detailed assay preparation method/
18. Justify the analytical method verification studies without performing test or specificity and precision. Further also specify the exact concentration of solutions of 50%, 100% and 150% solutions used in the analysis of accuracy and recovery test.	Firm has performed the specificity & precision but not submitted in the dossiers. Now, firm has submitted revised method verification and also explained the concentration of solutions used for accuracy & recovery test.
19. Provide COA of ref std./working std. actually used in the analysis of drug product in section 3.2.P.6	Firm has submitted the COA of working standard used in the analysis of drug product.
20. You have provided batch release certificate for different batches in section 3.2.P.5.4 while the stability study data of different batches is submitted in section 3.2.P.8.3. Clarification is required in this regard.	Firm has submitted the batch release certificates as per stability study batches.
21. Provide batch size of batch D-006 in terms of number of bottles instead of providing batch size in terms of kg.	Firm has submitted the corrected batch size as number of bottles instead of Kg.
22. You have submitted that API lot in manufacturing of stability batches is 18CF10035 while submitted COA of totally different batches in section 3.2.s.4.4. Justify why data was not submitted in line with guidance document issued by registration board.	Firm has explained that the COA of API lot was not cross checked with the stability batches at that time. Now the aligned COA submitted by the firm.
23. Justify why only 3 Chromatograms of the Std. Solution was run while USP General Chapter <621> Recommends that five replicates of Std. solution should be used for System Suitability Studies.	Firm has submitted the system suitability data as per USP recommendations.
24. Provide raw data sheets showing calculation of the results during the stability studies for all the batches.	Firm has submitted the raw data sheets along with stability data.
25. Justify why the Stability Study Data in Sec. 3.2.P.8.3 is not Submitted as per the Guidance Document Issued by Reg. Board	Firm has explained that the stability documents was not established as per guidance documents. Now, firm submitted the data on correct format.
 26. Submit Stability Study data in Sec. 3.2.P.8.3 as per the Checklist Approved by The Reg. Board in its 296th meeting and CTD Guidance Document, Which Includes the Following. Reference of Previous Approval of Applications with Stability Study data of the Firm (if any) Documents for the Procurement of API with Approval from DRAP (In case of Import) Compliance Record of HPLC Software 21CFR and Audit Trail Reports on Product Testing. 	 Firm has submitted that We have already approved products are Flunaz Dry Susp, Erymac Dry Susp & Ciprobio 125mg & 250 Dry Susp. Purchase invoice from Saakh pharma provided. 21CFR compliance of HPLC & Audit trail has been provided

27. Justify why BMR of different batches is submitted than that for which Stability Studies were conducted.	Firm has justify that we did not cross checked the batch numbers in BMRs & Stability data. Now it's been aligned, relevant BMRs.
28. Justify the criteria for selecting batch number and batch size of your product, since different format of batch numbers have been used for different batches, while significant difference in batch size also exist among various production scale batches.	Firm has justified that the stability of concerned product is selected for three consecutive batches of same strength and same dosage form regardless of the time frame. E.g. 03 consecutive batches may run at different time points based on Planned production or need. Since batch numbers are allocated in sequence of a dosage form continuously and hence the batch numbers of the stability batches may differ. E.g. Batches no of Lazma cream 15g may be followed by Lazma Cream 30g and so on. The Batch size of the stability batches of the same product must be of same size According to the validation SOP. However in our old SOP(old batches) this practice was not followed and batches of various batch sizes were used in validation study. Stability of those consecutive batches are selected by QA foe which the lot number of API Utilised is same.

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.

271.	Name, address of Applicant / Marketing Authorization Holder	M/s Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura	
	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) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 10-11-2020.	
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio- Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.	
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio- Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral 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. 17790: 25-06-2021
Details of fee submitted	PKR 50,000/-: 09-04-2021
The proposed proprietary name / brand name	VARICEF 200mg/5ml Dry Suspension
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate200mg
Pharmaceutical form of applied drug	Almost pink colored powder having strawberry flav powder for reconstitution
Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
Reference to Finished product specifications	USP
Proposed Pack size	30 ml
Proposed unit price	As per SRO
The status in reference regulatory authorities	Cefixime suspension (USFDA Approved)
For generic drugs (me-too status)	Cefim suspension by Hilton
Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Wes Industrial Zone, Port Qasim, Karchi.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS template. Firm has summarized information relate nomenclature, structure, general properties, solubility physical form, manufacturers, description manufacturing process and controls, impurity specifications, analytical procedures and its validate batch analysis and justification of specification reference standard, container closure system stability studies of drug substance and drug product
Module-III Drug Substance:	Firm has submitted detailed data for drug substance of related to nomenclature, structure, general propert solubilities, physical form, manufacturers, descript of manufacturing process and controls, impurit specifications, analytical procedures and its validate batch analysis and justification of specificat reference standard, container closure system stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batched drug substance at both accelerated as well as real to 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 time stability data is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65 \pm \text{RH}$ for 24 months.
Module-III Drug Product:	Firm has submitted data of drug product including description, composition, pharmaceutical developm manufacture, manufacturing process and process control, process validation protocols, control excipients, control of drug product, specification analytical procedures, validation of analytical procedures, batch analysis, justification specifications, reference standard or materic container closure system and stability.
Pharmaceutical Equivalence and Comparativ Dissolution Profile	re Firm has submitted results of pharmaceur equivalence for all the quality tests for their pro-

			Π,	against Cefspan dry sus	nancion
	A	1-4:/:6:4:			•
	*		Firm has submitted verification studies of the drug substance and the drug product.		
		STABILITY S	STU	DY DATA	
Manufacturer of API		Saakh Pharma (Pvt) L Karchi.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.		
API	Lot No.	18CF10035	18CF10035		
	cription of Pack ntainer closure system)	Alu-alu blister	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 (Months) Real Time: 0, 3, 6 (Months)		
Batc	h No.	553	589		597
Batc	h Size	7500 packs		7500 packs	7500 packs
Man	ufacturing Date	05-2018		08-2018	09-2018
Date	of Initiation	10-05-2018	31-08-2018		28-09-2018
No.	of Batches			03	
DOCUMENTS / DATA TO BE PROVIDED A		AL	ONG WITH STABIL	ITY STUDY DATA	
1.	Reference of previous apstability study data of the	proval of applications wit firm (if any)	th		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		ty A	Additional Director DR	y of GMP certificate issued by AP, Karachi dated 23-06-2020. as granted based on inspection
3. Documents for the procurement of API with approval from DRAP (in case of import).		al			
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		ta b		plete record of testing of all data sheets, COA and summary	
5.	Compliance Record of HP trail reports on product tes	LC software 21CFR & aud sting	lit N	NA	
humidity monitoring of stability chambers (real time		ne to		cord of digital data logger for ty monitoring of real time and mbers.	

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit valid contract manufacturing agreement between the contract giver and contract acceptor.
- Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.
- Submit label claim in module 1 as per the reference product along with submission of requisite fee.
- You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in USP. Revise the specifications along with submission of requisite fee.

- The drug substance manufacturer has claimed both BP and USP specifications for the drug substance, provide scientific justification in this regard.
- The drug substance manufacturer has claimed USP specifications for the assay method, while the submitted method is different from USP in terms of column specifications including column length and pore size. Justification is required in this regard.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Submit data in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that "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, since the submitted COA of three batches of API are of 2020 while the drug product batches were manufactured in 2019.
- Justify how your unit formula containing 1.368gm of drug substance is equivalent to 200mg cefixime base per 5ml after reconstitution. Further specify which is the unit which has been taken as reference for your formulation.
- Justify the formulation which is different in terms of qualitative composition from that of innovator product Suprax suspension.
- Innovator product has not used sodium citrate which is used in your formulation as preservative along with sodium benzoate. Justify the use of two different preservatives without determining the preservative effectiveness.
- The acceptance criteria for pH is 2.5 to 4.5 while your compatibility results specifies that after reconstitution with the recommended diluent / solvent, the pH is 5.08 which lies outside the acceptance criteria. Justify how you have passed this formulation and performed stability studies on the same formulation.
- The process validation studies have been conducted on three batches having 5000 bottles batch size. While the batch size of the commercial batches for which stability study data is submitted, ranges from as low as 3000 and as high as 10,000 bottles. Justification is required in this regard.
- Submit detailed method of analysis of the drug product in section 3.2.P.5.2 instead of submitting print of USP monograph.
- Submit exact details of the assay preparation since the words "*Reconstitute sample as directed n the labelling*" should not be used in the method adopted by a firm. Instead provide details about the exact diluent along with volume in which reconstitution is to be carried out.
- Justify the analytical method verification studies without performing test or specificity and precision. Further also specify the exact concentration of solutions of 50%, 100% and 150% solutions used in the analysis of accuracy and recovery test.
- Provide COA of the reference standard / working standard actually used in the analysis of drug product in section 3.2.P.6.
- You have provided batch release certificate for different batches in section 3.2.P.5.4 while the stability study data of different batches is submitted in section 3.2.P.8.3. Clarification is required in this regard.
- Provide batch size of Batch D-006 in terms of number of bottles instead of providing batch size in terms of Kg.
- You have submitted that API lot used in manufacturing of stability batches is 18CF10035 while submitted COA of totally different batches in section 3.2.S.4.4. Justify why data was not submitted in line with the guidance document issued by Registration Board.
- Justify why only 3 chromatographs of the standard solution was run while USP General chapter <621> recommends that five replicates of standard solution should be used for system suitability studies.
- Provide raw data sheets showing calculation of the results during the stability studies for all batches.
- Justify why the stability study data is section 3.2.P.8.3 is not submitted as per the guidance document issued by Registration Board.

- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
 - Reference of previous approval of applications with stability study data of the firm (if any)
 - O Documents for the procurement of API with approval from DRAP (in case of import).
 - o Compliance Record of HPLC software 21CFR & audit trail reports on product testing
- Justify why BMR of different batches is submitted than that for which stability studies were conducted.
- Justify the criteria for selecting batch number and batch size of your product, since different format of batch numbers have been used for different batches, while significant difference in batch size also exist among various production scale batches.

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

Response by the Firm:

	Deficiencies/ Short-comings	Justifications
1.	Submit differential fee for the registration of applied product,	Firm has submitted the differential fee.
1.	since the notification for revision of fee vide SRO No. F.7-	Thin has submitted the differential fee.
	11/2012-B&A/DRA was published on 7 th May 2021 while this	
	application was received R&I section of DRAP after 7 th May	
	2021.	
2.	Submit valid contract manufacturing agreement between the	Firm has submitted the valid contract.
	contract giver and contract acceptor.	This has saointeed the valid contract.
3.	Submit module 1 as per the CTD guidance document approved	Firm has submitted the Module 1 as per CTD
	by Registration Board by providing all the information and	guidance document.
	documents in relevant sections / sub-sections instead of	6
	referring to annexures.	
4.	Submit label claim in Module 1 as per the reference product	Firm has submitted the label claim as per reference
	along with submission of requisite fee.	product.
5.	You have mentioned Innovator's Specs in Sec. 1.5.6 in Module	Firm has explained that Innovator's specs was
	1 while the Drug Product Monograph is available in USP.	written mistakenly in Sec 1.5.6. Rest of the dossier
	Revise the Specs. Along with Submission of Requisite Fee.	is of USP specs already. Corrected Sec 1.5.6 has
		been attached.
6.	The drug substance manufacturer has claimed both BP and USP	Drug substance manufacturer used to follow both
	specs. For the assay method, while the submitted method is	specs. However, they have performed on USP for
	different from USP in terms of column specs including column	our product.
	length and pore size. Justification is required in this regard.	
7.	The drug substance manufacturer has claimed USP	Firm has explained that mistake was from the drug
	specifications for the Assay method, while the submitted	substance manufacturer. They have corrected the
	method is different from USP in terms of column specifications	assay method.
	including column length and pore size. Justification is required.	
8.	Submit data in sec. 3.2.S.4.1 as per the guidance doc. approved	Firm has submitted copies of drug substance specs
	by the reg. board which specifies that "copies of drug substance	and analytical procedure used for routine testing of
	specs and analytical procedure used for routine testing of API by both drug substance and drug product manufacturer is	API by both drug substance and drug product manufacturer.
	required.	manuracturer.
9.	Submit data in section 3.2.S.4.3 as per the decision of 293 rd	Firm has submitted analytical method verification
٦.	meeting of registration board which states that the "analytical	studies including specificity, accuracy and
	method verification studies including specificity, accuracy and	repeatability (method precision) performed by the
	repeatability (method precision) performed by the drug product	drug product manufacturer
	manufacturer for both compendial as well as non-	drug product manufacturer
	drug substance(s) shall be submitted". Further justify how the	
	analysis of drug substance was conducted without performing	
	verification studies of analytical method of drug substance.	
10.	Submit data in section 3.2.S.4.4 as per the guidance document	Firm has submitted the results analyses of relevant
	approved by registration board which specifies that "provide	batch(s) of drug substance performed by the drug
	results analyses of relevant batch(s) of drug substance	product manufacturer used during product
	performed by the drug product manufacturer used during	development and stability studies, along with
	product development and stability studies, along with COA of	COA of same batch from API manufacture.
	same batch from API manufacture, since the submitted COA	
	of three batches of API are of 2020 while the drug product	
	batches were manufactured in 2019."	

11.	Justify how your unit formula containing 1.368gm of drug substance is equivalent to 200mg cefixime base per 5ml after reconstitution. Further specify which is the unit which has been taken as reference for your formulation.	Firm has submitted the calculation as per reference formulation.
	Justify the formulation which is different in terms of qualitative composition from that of innovator product suprax suspension. Innovator product has not used sodium citrate which is used in your formulation as preservative along with sodium benzoate. Justify the use of two different preservative without determining preservative effectiveness.	Firm has submitted the rationale of using excipients in its formulation. Firm has justify that sodium citrate has been used as buffering agent for pH control, not the preservative.
14.	The acceptance criteria for pH is 2.5 to 4.5 while your compatibility results specifies that after reconstitution with the recommended diluent/solvent, the pH is 5.08 which lies outside the acceptance criteria. Justify how you have passed this formulation and performed stability studies on same formulation.	Firm has justify that it was typo error in pH. Revised pharmaceutical development document has been submitted.
15.	The process validation studies have been conducted on three batches having 5000 bottles batch size. while the batch size of commercial batches for which stability study data is submitted, ranges from as low as 3000 and as high as 10,000 bottles. Justification is required in this regard.	Firm has explained that batch sizes wasn't harmonized for submitted stability batches but from these new submitted batches we have standardize the batch size onward.
16.	Submit detailed method of analysis of drug product in section 3.2.P.5.2 instead of submitting print of USP monograph.	Firm has submitted the detailed method of analysis in 3.2.P.5.2
	Submit exact details of assay preparation since words "reconstitute sample as directed in the labeling" should not be used in the method adopted by firm instead provide details about the exact diluent along with volume in which reconstituted is to be carried out.	Firm has submitted the detailed assay preparation method/
18.	Justify the analytical method verification studies without performing test or specificity and precision. Further also specify the exact concentration of solutions of 50%, 100% and 150% solutions used in the analysis of accuracy and recovery test.	Firm has performed the specificity & precision but not submitted in the dossiers. Now, firm has submitted revised method verification and also explained the concentration of solutions used for accuracy & recovery test.
19.	Provide COA of ref std./working std. actually used in the analysis of drug product in section 3.2.P.6	Firm has submitted the COA of working standard used in the analysis of drug product.
20.	You have provided batch release certificate for different batches in section 3.2.P.5.4 while the stability study data of different batches is submitted in section 3.2.P.8.3. Clarification is required in this regard.	Firm has submitted the batch release certificates as per stability study batches.
21.	Provide batch size of batch D-006 in terms of number of bottles instead of providing batch size in terms of kg.	Firm has submitted the corrected batch size as number of bottles instead of Kg.
	You have submitted that API lot in manufacturing of stability batches is 18CF10035 while submitted COA of totally different batches in section 3.2.s.4.4. Justify why data was not submitted in line with guidance document issued by registration board.	Firm has explained that the COA of API lot was not cross checked with the stability batches at that time. Now the aligned COA submitted by the firm.
	Justify why only 3 Chromatograms of the Std. Solution was run while USP General Chapter <621> Recommends that five replicates of Std. solution should be used for System Suitability Studies.	Firm has submitted the system suitability data as per USP recommendations.
	Provide raw data sheets showing calculation of the results during the stability studies for all the batches.	Firm has submitted the raw data sheets along with stability data.
	Justify why the Stability Study Data in Sec. 3.2.P.8.3 is not Submitted as per the Guidance Document Issued by Reg. Board	Firm has explained that the stability documents was not established as per guidance documents. Now, firm submitted the data on correct format.
27. 28.	Submit Stability Study data in Sec. 3.2.P.8.3 as per the Checklist Approved by The Reg. Board in its 296 th meeting and CTD Guidance Document, Which Includes the Following. Reference of Previous Approval of Applications with Stability Study data of the Firm (if any) Documents for the Procurement of API with Approval from DRAP (In case of Import) Compliance Record of HPLC Software 21CFR and Audit Trail Reports on Product Testing.	 Firm has submitted that We have already approved products are Flunaz Dry Susp, Erymac Dry Susp & Ciprobio 125mg & 250 Dry Susp. Purchase invoice from Saakh pharma provided. 21CFR compliance of HPLC & Audit trail has been provided

30. Justify why BMR of different batches is submitted than that for which Stability Studies were conducted.	Firm has justify that we did not cross checked the batch numbers in BMRs & Stability data. Now it's been aligned, relevant BMRs.
31. Justify the criteria for selecting batch number and batch size of your product, since different format of batch numbers have been used for different batches, while significant difference in batch size also exist among various production scale batches.	Firm has justified that the stability of concerned product is selected for three consecutive batches of same strength and same dosage form regardless of the time frame. E.g. 03 consecutive batches may run at different time points based on Planned production or need.
	Since batch numbers are allocated in sequence of a dosage form continuously and hence the batch numbers of the stability batches may differ. E.g. Batches no of Lazma cream 15g may be followed by Lazma Cream 30g and so on. The Batch size of the stability batches of the same product must be of same size According to the validation SOP. However in our old SOP(old batches) this practice was not followed and batches of various batch sizes were used in validation study. Stability of those consecutive batches are selected by QA foe which the lot number of API Utilised is same.

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.

272.	Name, address of Applicant / Importer	M/s Sohail Corporation Plot No. 474 Siraj Colony Moosa Lane Karachi.	
	Details of Drug Sale License of importer	License No: DHODSK(Drugs)/-433 Address: Plot No. 7, SR-5, Serai Quarters (Techno City) WH-42, Ware House No. 42, Karachi Address of Godown: NA Validity: 19-11-2022. Status: Drug License by way of wholesale	
	Name and address of marketing authorization holder (abroad)	Anhui Chengshi Pharmaceutical Co. Ltd. No. 5068, Huaishang Road, Bengbu, Ahui Province China.	
	Name, address of manufacturer(s)	Anhui Chengshi Pharmaceutical Co. Ltd. No. 5068, Huaishang Road, Bengbu, Ahui Province China.	
	Name of exporting country	China.	
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized CoPP (CoPP does not bear any certificate number) dated 29-07-2021 for dexamethasone Sodium Phosphate Injection 4mg/ml. The certificate confirms the free sale status of the product along with GMP status of the manufacturer. The CoPP does not have any issuing authority instead name of the firm is mentioned in place of issuing authority.	
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized copy of Agency Agreement between Anhui Chengshi Pharmaceutical Co. Ltd. No. 5068, Huaishang Road, Bengbu, Ahui Province China and Sohail Corporation Plot No. 474 Siraj Colony Moosa Lane Karachi. The agreement is valid for 5 years from 1 July	

	2020 and specifies DEXAMETHASONE Sodium Phosphate Injection 4mg/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 ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpoonly 	
Dy. No. and date of submission	Dy No 30797: 19-11-2021	
Details of fee submitted	PKR 100,000/-: 07-04-2021 PKR 50,000/-: 07-06-2021	
The proposed proprietary name / brand name	DEXAMETHASONE Sodium Phosphate Injection 4mg/ml	
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml ampoule contains: Dexamethasone sodium phosphate4mg	
Pharmaceutical form of applied drug	Clear colourless solution in glass ampoule	
Pharmacotherapeutic Group of (API)	Glucocorticoid	
Reference to Finished product specifications	USP	
Proposed Pack size	4mg/1ml glass ampoule	
Proposed unit price	No submitted by the firm	
The status in reference regulatory authorities	DBL DEXAMETHASONE SODIUM PHOSPHATINJECTION 4mg/1mL (TGA Approved).	
For generic drugs (me-too status)	Dexonil 4mg Injection by Vision pharma (Reg#037570)	
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templa Firm has summarized information related to nomenclatu structure, general properties, solubilities, physical for manufacturers, description of manufacturing process a controls, impurities, specifications, analytical procedur and its validation, batch analysis and justification specification, reference standard, container closure syste and stability studies of drug substance and drug product	
Name, address of drug substance manufacturer	Zhejiang Xianju Pharmaceutical Co. Ltd. No. 1 Xian Y Road, Xianju Zhejiang China.	
Module-III Drug Substance:	Firm has submitted detailed drug substance data related nomenclature, structure, general properties, solubilities physical form, manufacturers, description manufacturing process and controls, impurities specifications, analytical procedures and its validation batch analysis and justification of specification, referent standard, container closure system and stability studies drug substance.	
Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches of A	

	stability data is conducted at 25°C / 60% RH. The stability study data is till 48 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against following products: Dexamethasone sodium phosphate injection of Aspen Pharma Trading Limited. Dexamethasone sodium phosphate injection of Xinxiang Changle Pharmaceutical Co. Ltd. Dexamethasone sodium phosphate injection of Zhejiang Xianju Pharmaceutical Co. Ltd. Dexamethasone sodium phosphate injection of Shanghai Tongyong Pharmaceutical Co Ltd.
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Glass ampoule in colour printed box
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 36 months at 30±2°C, 75±5%RH and 6 months at 40°C±75%RH for three batches.

Evaluation by PEC:

~	T.,	
Sr. No	Observations communicated	Response by the firm
1.	The label claim of the innovator's product specifies that each ml ampoule contains	In China, the content of dexamethasone sodium phosphate injection is shown by the dexamethasone sodium phosphate
	dexamethasone sodium phosphate equivalent to	instead of dexamethasone
	4 mg of dexamethasone phosphate, while your	phosphate. So the label and CoPP specify content of
	label claim and CoPP specifies that the	dexamethasone sodium phosphate injection by the
	injection contains 4mg dexamethasone sodium	dexamethasone sodium phosphate.
	phosphate per ml ampoule.	In fact, the dexamethasone sodium phosphate injection
		4mg/1ml is same with the innovator's product which specifies
		that each ml ampoule contains dexamethasone sodium
		phosphate equivalent to 4mg of dexamethasone phosphate.
		Please reference the following explains for details.
		In the USP "DEFINITION": Dexamethasone Sodium
		Phosphate Injection is a sterile solution of Dexamethasone Sodium Phosphate in Water for Injection. It contains NLT
		90.0% and NMT 115.0% of the labeled amount of
		dexamethasone
	phosphate (C22H30FO8P), present as the disodium salt. The molecular weight of C22H30FO8P is 472.4. The molecular	
	weight of C22H28FNa2O8P is 516.4. For our product: the	
	labeled amount is 4mg/ml of Dexamethasone Sodium	
	Phosphate equivalent to 3.7mg/ml of dexamethasone	
	phosphate. According to the USP standard, the qualified	
	content range of dexamethasone phosphate is 3.33mg/ml to	
	4.26mg/ml.	
		For innovator's product: the labeled amount is 4mg/ml of
		dexamethasone phosphate. According to the USP standard, the
		qualified content range of dexamethasone phosphate is
		3.6mg/ml to 4.6mg/ml.

		So we just have to ensure that the content of our product is within this range of dexamethasone phosphate 3.60mg/ml-4.26mg/ml. Our product will be same same with the innovator's
		product. And we will clearly indicate content of dexamethasone
		phosphate (3.60mg/ml-4.26mg/ml) in our drug product leaflet.
2.	Master formulation, composition and CoPP specifies that each vial contains 4mg dexamethasone sodium phosphate while as per innovator's product each vial contains 4mg of dexamethasone phosphate. Clarification is required in this regard.	In China, the content of dexamethasone sodium phosphate injection is shown by the dexamethasone sodium phosphate instead of dexamethasone phosphate. So the label and CoPP specify content of dexamethasone sodium phosphate injection by the dexamethasone sodium phosphate. In fact, the dexamethasone sodium phosphate injection
		4mg/1ml is same with the innovator's product which specifies that each ml ampoule contains dexamethasone sodium phosphate equivalent to 4mg of dexamethasone phosphate. Please reference the following explains for details.
3.	Provide report of validation studies of the analytical method of drug product since you have only submitted brief summary.	The analytical procedure of the Dexamethasone Sodium Phosphate injection 4mg/1ml is according to the USP. so we only do the assay validation. the summary is as follows. The detail information please check the "Attachment 2 Validation of Analytical Procedures of Dexamethasone Sodium Phosphate 4mg/1ml".
4.	Address of the applicant mentioned in module 1 and also specified in agency agreement is "Sohail Corporation Plot No. 474 Siraj Colony Moosa Lane Karachi" while the address of the firm as per Drug Sale License is "Sohail Corporation Plot No. 7, SR-5, Serai Quarters (Techno City) WH-42, Ware House No. 42, Karachi". Clarification is required in this regard.	The address of applicant (Sohail Corporation) has changed. As this is our previous address Sohail Corporation Plot No.474 Siraj Colony Moosa Lane, Karachi-Pakistan" Now the current address is "Sohail Corporation Plot No.7, SR-5, Serai Quarters (Techo City) WH-42, Ware House No. 42, Karachi"
5.	The submitted CoPP does not bear any certificate number, moreover issuing authority of the CoPP is mentioned as Anhui Chengshi Pharmaceutical Co. Ltd which is the product license holder and manufacturer in China. Clarification is required in this regard.	First, our COPP is notarized by the Notary Office, and then certified by the Ministry of Foreign Affairs and the Pakistan Consulate. The Notary Office is established in accordance with the 《Notary Law of the People's Republic of China》. The notary office is a non-profit verification institution that independently exercises the notarization function and assumes civil liability. When the Notary Office notarizes the COPP, the Notary Office will first communicate with the corresponding regulatory authorities to verify whether the manufacturer has the qualification and record to produce and sell the product. If the manufacturer has the corresponding qualification and record and the situation is true, the corresponding COPP will be notarized and the notarial certificate will be issued. Then the Ministry of Foreign Affairs verified the notarial certificate, and if the notarial certificate is true, the notarial certificate will be proved. Finally, the corresponding consulate will verify the notarial certificate that have been certified by the Ministry of Foreign Affairs. And we promise to keep renewing the COPP. As soon as we get the renewed COPP, we will send it to you.

Decision: Deferred for following submissions:

- Clarification of the label claim and master formulation of the applied product in line with the innovator's product formulation.
- Full fee of registration for change in the address of the importer / applicant.
- Afresh Sole agency agreement in name of the applicant with new address.
- Clarification since the submitted CoPP does not bear any certificate number, and the issuing authority of the CoPP is mentioned as Anhui Chengshi Pharmaceutical Co. Ltd which is the product license holder and manufacturer in China

Case no. 01 Registration applications of newly granted DML or New section (Human)

a. New DML

M/s Nagarsons Pharmaceutical (Pvt) Ltd . (New DML)

Firm has submitted copy of Acknowledgment of receipt of application for grant of DML by way of formulation to M/s Nagarsons Pharmaceuticals dated 19-02-2021 from Secretary Central Licensing Board. The letter specifies that CLB in its 278th meeting held on 10th and 11th December 2020 has approved the grant of DML in the name of M/s Nagarsons Pharmaceuticals for following sections:

- 1. Tablet (General)
- 2. Tablet (Psychotropic)
- 3. Capsule (General)
- 4. Cream /ointment/Lotion/Gel

Sr. No	Section	Molecules for consideration in 327 th meeting	Products for consideration in 327 th meeting
1	Tablet (General)	01	02

Name, address of Applicant / Marketing Authorization Holder	M/s Nagarsons Pharmaceutical (Pvt) Ltd Plot No.34, street No. NS-2, National Industries Zor Rawat Islamabad.
Name, address of Manufacturing site.	M/s Nagarsons Pharmaceutical (Pvt) Ltd Plot No.34, street No. NS-2, National Industries Zor Rawat 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
Dy. No. and date of submission	Dy. No. 5894 dated 02-03-2023
Details of fee submitted	PKR 30,000/-: Deposit slip # 543749515652
The proposed proprietary name / brand name	Relpride Tablet 25mg
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains; Levosulpiride 25 mg
Pharmaceutical form of applied drug	Tablet
Pharmacotherapeutic Group of (API)	Propulsive/Prokinetics
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	Levosulpiride Aristo 25 mg tablets, AIFA approved.

		T
For generic drugs (me-too status)		Sulvoric 25mg Tablet of M/s High-Q Reg. No.070484
	ned product manufacturer	New license granted on 19th Feburary 2021.
Name and address of AF	PI manufacturer.	M/s Alcon Biosciences Private Ltd. A-1/2014, Phase-III, G.I.D.C Vapi, District Valsad Gujrat, India.
Module-II (Quality Over	rall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, 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 Substa	ance)	Official monograph of Levosulpiride is not present in any pharmacopeia. 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 verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies		Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 48 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months Batches: (ALC/LSP/170203, ALC/LSP/170204, ALC/LSP/170205)
Module-III (Drug Produ	ct):	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 equivale dissolution profile	ence and comparative	Pharmaceutical Equivalence is established against the brand that is LEVOPRAID 25 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., B. No. AP0909Q by performing quality tests (description, Assay, Dissolution). CDP has been performed against the same brand that is LEVOPRAID 50 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
Analytical method valid	ation/verification of product	
	STABILITY ST	TUDY DATA
Manufacturer of API	M/s Alcon Biosciences Pri Valsad Gujrat, India.	vate Ltd. A-1/2014, Phase-III, G.I.D.C Vapi, District
API Lot No.	BLEVS210029	
Description of Pack (Container closure system)	Alu-Alu blister packed	
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65^{\circ}$	5% ± 5%RH

		Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$	75% ± 5%RH			
Time	e Period	Real time: 6 months Accelerated: 6 months				
Freq	uency	Accelerated: 0, 3, 6 (Mont Real Time: 0, 3, 6 (Month				
Batc	h No.	T001	T002	T003		
Batc	h Size	2000	2000	2000		
Man	ufacturing Date	01-22	01-22	01-22		
Date	of Initiation	05-01-22	05-01-22	05-01-22		
No. o	of Batches		03			
		Administrati	ve Portion			
1.		revious approval of applications with data of the firm (if any)				
2.	manufacturer is	PI/ DML/GMP certificate of API ssued by concerned regulatory untry of origin.	Copy of GMP certificate Noby Food and Drug Control A Gandhinagar, Gujrat state In and valid until 21-10-2022.	dministration		
3.		the procurement of API with DRAP (in case of import).	Firm has submitted copy for AB/I/00101/21-22) dated: 0 DRAP Islamabad dated: 13-5 10Kg Levosulpiride (Batch#	1-09-2021 attested by 9-2021 specifying import of		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		The firm has submitted supported by attested re chromatograms, raw data sl sheets etc.	espective documents like		
5.		ecord of HPLC software 21CFR & rts on product testing	Not submitted			
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Not submitted			
Rem	arks of Evaluato	r:				
S.N		Shortcomings Communicated				
1.	1.3.5.	GMP inspection report/ GMP cert last three years shall be submitted.	iticate of the manufacturing u	anit issued within the		
2.	1.6.5	certificate of the Drug Substance m of country of origin	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority			
3.	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			
4.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.				
5.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.				
6.	3.2.P.2.2.1	 Justification shall be submitted for not carrying the CDP against the innovator's brand Details and picture/image/ snapshot of product against which Pharmaceutical Equivalence and CDP conducted. 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of Comparative dissolution. 				

		 As per Innovator product in CDP percentage dissolved is higher than 85% at 15 minutes in all the 03 media i.e HCl 0.1N, 4.5 and pH 6.8 while as per your CDP data higher than 85% at 30 minutes. Justification is required.
7.	3.2.P.5.1	Applied formulations in section 1.5.6 are Innovator while in this section USP specifications are clamed. Clarify.
8.	3.2.P.5.3	Analytical method verification submitted while product is not available in any pharmacopeia.
9.	3.2.P.8	 Documents for the procurement of API with approval from DRAP as submitted Commercial Invoice is not in readable form Batch size is not mentioned 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)

ecisi	sion: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
74.	Name, address of Applicant / Marketing Authorization Holder	M/s Nagarsons Pharmaceutical (Pvt) Ltd Plot No.34, street No. NS-2, National Industries Zone, Rawat Islamabad.	
	Name, address of Manufacturing site.	M/s Nagarsons Pharmaceutical (Pvt) Ltd Plot No.34, street No. NS-2, National Industries Zone, Rawat 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	
	Dy. No. and date of submission	Dy. No. 5895 dated 02-03-2023	
	Details of fee submitted	PKR 30,000/-: Deposit slip # 91709832	
	The proposed proprietary name / brand name	Relpride Tablet 50mg	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains; Levosulpiride 50 mg	
	Pharmaceutical form of applied drug	Tablet	
	Pharmacotherapeutic Group of (API)	Propulsive/Prokinetics	
	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	Levosulpiride Aristo 50 mg tablets, AIFA Italy approved.	
	For generic drugs (me-too status)	Sulvoric 50mg Tablet of M/s High-Q Reg. No.070485	
	GMP status of the Finished product manufacturer	New license granted on 19th Feburary 2021.	
	Name and address of API manufacturer.	M/s Alcon Biosciences Private Ltd. A-1/2014, Phase-III, G.I.D.C Vapi, District Valsad Gujrat, India.	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's,	

Module III (Drug Substa			physical form, manufacturer manufacturing process and of specifications, analytical pro- verification, batch analysis a specification, reference stand system and stability studies of product is submitted.	controls, impurities, ocedures and its and justification of dard, container closure
		ance)	Official monograph of Levosulpiride is not pr any pharmacopeia. The firm as submitted deta nomenclature, structure, general properties, so physical form, manufacturers, description of manufacturing process and controls, tests for it specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closesystem and stability studies of drug substance	
	Stability studies		Stability study conditions: Real time: 30°C ± 2°C / 65% Accelerated: 40°C ± 2°C / 75 Batches: (ALC/LSP/17020 ALC/LSP/170205)	$5\% \pm 5\%$ RH for 6 months
Module-III (Drug Product):		ict):	The firm has submitted description of manufacturi impurities, specifications (including dissolution test medium) and its verification justification of specificat container closure system ar product.	ing process and controls, , analytical procedure ing at acidic and buffer studies, batch analysis and tion, reference standard,
	Pharmaceutical equivalence and comparative dissolution profile		Pharmaceutical Equivalence the brand that is LEVOPRA. Pacific Pharma (Pvt.) Ltd., b performing quality tests (des Dissolution). CDP has been performed agais LEVOPRAID 50 mg Tabl. Pharma (Pvt.) Ltd., in Acid is buffer (pH 4.5) & Phosphate	ID 50 mg Tablets by M/s by scription, Assay, ainst the same brand that lets by M/s Pacific media (pH 1.2), Acetate
	Analytical method valid	lation/verification of product	X / X	<u> </u>
		STABILITY ST	TUDY DATA	
Manuf	acturer of API	M/s Alcon Biosciences Priv Valsad Gujrat, India.	vate Ltd. A-1/2014, Phase-III	, G.I.D.C Vapi, District
API Lo	ot No.	BLEVS210029		
Description of Pack (Container closure system) Alu-Alu		Alu-Alu blister packed		
, ,		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65$		
Time I	Period	Real time: 6 months Accelerated: 6 months		
Freque	ency	Accelerated: 0, 3, 6 (Month Real Time: 0, 3, 6 (Months	•	
Batch	No.	T004	T005	T006

Batch Size		2500/2000	2500/2000	2500/2000
Manufacturing Date		01-22	01-22	01-22
Date o	of Initiation	05-01-22	05-01-22	05-01-22
No. of	Batches		03	
		Administrativ	ve Portion	
1.	Reference of previous approximation study data of the	proval of applications with firm (if any)		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Copy of GMP certificate Not by Food and Drug Control A Gandhinagar, Gujrat state Incand valid until 21-10-2022.	dministration
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.		The firm has submitted supported by attested re chromatograms, raw data sh sheets etc.	spective documents like
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Not submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Not submitted	

Remarks of Evaluator:

Remar	emarks of Evaluator:			
S.No	Section	Shortcomings Communicated		
1.	1.3.5.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be 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		
3.	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		
4.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.		
5.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.		
6.	3.2.P.2.2.1	 Justification shall be submitted for not carrying the CDP against the innovator's brand Details and picture/image/ snapshot of product against which Pharmaceutical Equivalence and CDP conducted. 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of Comparative dissolution. As per Innovator product in CDP percentage dissolved is higher than 85% at 15 minutes in all the 03 media i.e HCl 0.1N, 4.5 and pH 6.8 while as per your CDP data higher than 85% at 30 minutes. Justification is required. 		
7.	3.2.P.5.1	Applied formulations in section 1.5.6 are Innovator while in this section USP specifications are clamed. Clarify.		
8.	3.2.P.5.3	Analytical method verification submitted while product is not available in any pharmacopeia.		
9.	3.2.P.8	Documents for the procurement of API with approval from DRAP.(Clear Commercial Invoice).		

- Batch size is not mentioned
- 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.

b. New/Additional section(s)

M/s PDH Laboratories Pvt Ltd. (New Section)

CLB in its 285th meeting held on 17th & 18th March 2022, has approved the following 01 additional sections of M/s PDH Laboratories Pvt Ltd.

1.Oral liquid Section (General) Additional

	Sr. No	Section	Molecules for consideration in 327 th meeting	Products for consideration in 327 th meeting	
	1	Oral liquid Section (General)	01	02	
275.		, address of Applicant / Marketing orization Holder	M/s PDH Laboratorie 9.5 km, Sheikhupura l	es Pvt Ltd. Road, Lahore, Pakistan	
	Name,	, address of Manufacturing site.	M/s PDH Laboratorie 9.5 km, Sheikhupura l	es Pvt Ltd. Road, Lahore, Pakistan	
	Status	of the applicant	☑ Manufacturer☐ Importer☐ Is involved in none	e of the above (contract giver)	
	Status	of application	☐ New Drug Product ☐ Generic Drug Prod		
	Intende	led use of pharmaceutical product	☑ Domestic sale☐ Export sale☐ Domestic and Export	ort sales	
	Dy. No	o. and date of submission	Dy. No. 3222 dated (03-02-2023	
	Details	s of fee submitted	PKR 30,000/-: Depo	osit slip # 708047908	
	The pr	roposed proprietary name / brand name	Temol Suspension 120	0mg/5ml	
		gth / concentration of drug of Active naceutical ingredient (API) per unit	Each 5ml Contains: Paracetamol120	Each 5ml Contains: Paracetamol120mg	
	Pharm	naceutical form of applied drug	Clear, viscous liquid l	Clear, viscous liquid light orange to orange colour	
	Pharm	nacotherapeutic Group of (API)	Analgesic and Antipyretic		
	Refere	ence to Finished product specifications	USP		
	Propos	sed Pack size	1's x 60ml		
	Propos	sed unit price	As per SRO	As per SRO	
	The sta	atus in reference regulatory authorities		Paracetamol 120 mg/5 ml Oral Suspension by Pinewo Laboratories Limited, Ireland of MHRA approved.	
	For ge	eneric drugs (me-too status)	Calpol Pediatric Suspo Pakistan. No.000354	Calpol Pediatric Suspension of M/s GlaxosmithKline Pakistan. No.000354	
	GMP s	status of the Finished product manufacturer		ficate on the basis of Evaluate 2022 and valid for two years.	

			<u>, </u>
	Name and address of AP	I manufacturer.	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, Port Qasim Karachi.
	Module-II (Quality Overa	all Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, 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 Substan	nce)	Official monograph of Paracetamol(Actaminophen) is present in USP. 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 verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Module-III (Drug Product): Pharmaceutical equivalence and comparative dissolution profile		Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 18 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months Batches: (21GN60001, 21GN60002, 21GN60003)
			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 is established against the brand that is Calpol Suspension by M/s GSK Batch # 372R by performing quality tests (description, Identification, pH, Deliverable Volume, Viscosity, Microbial Enumeration, Assay)
	Analytical method valida	tion/verification of product	Method verification studies have submitted including accuracy, precision, specificity.
		STABILITY ST	TUDY DATA
Manuf	acturer of API	M/s Saakh Pharma (Pvt) La Address: C-7/1, Nwiz, Port	
API Lo	ot No.	21GN60187	
Description of Pack (Container closure system)			orange to orange colour sweet in taste filled in ambered I sealed with Aluminium cap, neatly labelled and packed on of a leaflet
Stabili	ty Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65$	
Time F	Period	Real time: 6 months Accelerated: 6 months	
Freque	ncy	Accelerated: 0, 3, 6 (Month Real Time: 0, 3, 6, 9, 12 (Month Real Time: 0, 3, 6, 9, 9, 12 (Month Real Time: 0, 3, 6, 9, 9, 12 (Month Real Time: 0, 3, 9, 9, 9, 9, 9, 9, 9, 9, 9, 9, 9, 9, 9,	

Batch	No.		T-006	T-007	T-008
Batch	Size		40 bottles	40 bottles	40 bottles
Manu	facturing Date		11-2021	11-2021	11-2021
Date of	of Initiation		10-12-2021	10-12-2021	10-12-2021
No. of	f Batches			03	
			Administrati	ve Portion	
1.	Reference of pr stability study of		proval of applications with firm (if any)		
2.		sued by co	GMP certificate of API oncerned regulatory igin.	Copy of cGMP certificate on conducted on 07-10-2022 an	
3.			rement of API with case of import).	Not submitted	
4.	attested respect	ive docum	will be supported by ents like chromatograms, immary data sheets etc.	The firm has submitted supported by attested re chromatograms, raw data shaheets etc.	espective documents like
5.	Compliance Re audit trail repor		PLC software 21CFR & uct testing	Not submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			The firm has submitted Reco for temperature and humidity chambers (real time and acce	monitoring of stability
	rks of Evaluato				
S.No			omings Communicated	nmeter of Analytical method	1::6:4: :4
1.	3.2.S.4.3	conduct determine replicate	conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).		
2.	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.			
3.	3.2.P.5.2	In Assa	y final concentrations is 0	.01mg/ml while 96 mg of pa .96mg 0.01mg/ml concentrati	
4.	3.2.P.5.3	conduct determi	In Drug Product Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates		
5.	3.2.P.8	Purchas	e Documents for Paracetam ance Record of HPLC softw	ol. are 21CFR & audit trail repor	ts on product testing
Decisi	on: Registration	n Board d	eferred the case for submi	ssion of reply to the above ci	ited shortcomings.
276.	Name, address Authorization I		ant / Marketing	M/s PDH Laboratories Pvt L 9.5 km, Sheikhupura Road, I	
	Name, address	of Manufa	acturing site.	M/s PDH Laboratories Pvt L 9.5 km, Sheikhupura Road, I	
	Status of the applicant		☑ Manufacturer☐ Importer☐ Is involved in none of the	above (contract giver)	
	Status of applic	cation		☐ New Drug Product (NDP))
L	ı				

	T
	☑ Generic Drug Product (GDP)
Intended use of pharmaceutical product	□ Domestic sale
	☐ Export sale
	☐ Domestic and Export sales
Dy. No. and date of submission	Dy. No. 7379 dated 14-03-2023
Details of fee submitted	PKR 30,000/-: Deposit slip # 3924666116
The proposed proprietary name / brand name	Temol DS Suspension 250mg/5ml
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Paracetamol250mg
Pharmaceutical form of applied drug	Clear, viscous liquid light orange to orange colour
Pharmacotherapeutic Group of (API)	Analgesic and Antipyretic
Reference to Finished product specifications	USP
Proposed Pack size	1's x 60ml
Proposed unit price	As per SRO
The status in reference regulatory authorities	Paracetamol 250 mg/5 ml Oral Suspension by Pinewood Laboratories Limited, Ireland of MHRA approved.
For generic drugs (me-too status)	Calpol 6 plus Suspension of M/s GlaxosmithKline Pakistan. No.000354
GMP status of the Finished product manufacturer	Copy of cGMP certificate on the basis of Evaluation conducted on 04-01-2022 and valid for two years.
Name and address of API manufacturer.	M/s Saakh Pharma (Pvt) Ltd Address: C-7/1, Nwiz, Port Qasim Karachi.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)	Official monograph of Paracetamol(Actaminophen) is present in USP. 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 verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 18 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months Batches: (21GN60001, 21GN60002, 21GN60003)
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 specifical container closure system ar product.	
	Pharmaceutical dissolution profi		nce and comparative	Pharmaceutical Equivalence the brand that is Calpol 6 Plu Batch # 372R by performing Identification, pH, Deliveral Microbial Enumeration, Ass	us Suspension by M/s GSK quality tests (description, ble Volume, Viscosity,
	Analytical method	od valida	tion/verification of product	Method verification studies accuracy, precision, specific	9
			STABILITY ST	UDY DATA	
Manuf	Cacturer of API		M/s Saakh Pharma (Pvt) La Address: C-7/1, Nwiz, Port		
API L	ot No.		21GN60187		
	ption of Pack iiner closure syste	em)		orange to orange colour sweet I sealed with Aluminium cap, on of a leaflet	
Stabili	ty Storage Condi	tion	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65$		
Time l	Period		Real time: 6 months Accelerated: 6 months		
Freque	ency		Accelerated: 0, 3, 6 (Month Real Time: 0, 3, 6 (Months		
Batch	No.		T-007	T-008	T-009
Batch	Size		40 bottles	40 bottles	40 bottles
Manufacturing Date			06-2022	06-2022	06-2022
Date o	f Initiation		20-06-2022	22-06-2022	24-06-2022
No. of	Batches			03	
			Administrativ	ve Portion	
1.	Reference of prestability study da		proval of applications with firm (if any)		
2.		sued by co	GMP certificate of API oncerned regulatory igin.	Copy of cGMP certificate or conducted on 07-10-2022 an	
3.	Documents for tapproval from D		rement of API with case of import).	Not submitted	
4.	attested respectiv	ve docum	will be supported by ents like chromatograms, ummary data sheets etc.	The firm has submitted supported by attested rechromatograms, raw data sheets etc.	espective documents like
5.	Compliance Recaudit trail report		PLC software 21CFR & uct testing	Not submitted	
6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		The firm has submitted Reco for temperature and humidity chambers (real time and acce	y monitoring of stability		
	rks of Evaluator				
1.	Section 3.2.S.4.3	In Drug	ed as per ICH Q2(R1)	nmeter of Analytical method guidelines. Which states	"a minimum of 9
		determi	nations covering the specific	ed range for the procedure (e.	g., 3 concentrations/3

		replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
2.	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.
3.	3.2.P.5.3	In Drug Product Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
4.	3.2.P.8	Purchase Documents for Paracetamol. 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

277.	Name and address of manufacturer/ Applicant	M/s. Relizon Pharmaceuticals, Plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore. (DML No. 000875) Tablet (general) Section		
	Brand Name + Dosage Form + Strength	PAROZON 12.5mg control release tablet		
	Composition	Each film coated control release tablet contains; Paroxetine HCl eq. to Paroxetine USP12.5mg		
	Diary No. Date of R & I & fee	Dy. No. 15502 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0826908 dated 05-03-2019, endorsed on 07.03.2019.		
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code: N06AB05		
	Type of Form	Form-5		
	Finished product Specification	USP Specifications.		
	Pack size & Demanded Price	10's. As per SRO.		
	Approval status of product in Reference Regulatory Authorities	PAXIL CR, Paroxetine hydrochloride (eq to base: 12.5mg, 25mg, 37.5mg) tablet extended release. USFDA Approved.		
	Me-too status	Seroxat CR tablet 12.5mg Reg. No. 043058 M/s GSK Karachi.		
	GMP status	Last inspection conducted on 08.06.2022. GMP status is good.		
	Remarks of the Evaluator			
	Decision: Approved.			
278.	Name and address of manufacturer/ Applicant	M/s. Relizon Pharmaceuticals, Plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore. (DML No. 000875) Tablet (general) Section		
	Brand Name + Dosage Form + Strength	RELDIC 100mg Tablet		
	Composition	Each tablet contains; Diclofenac sodium100mg		
	Diary No. Date of R & I & fee	Dy. No. 15503 dated 07.03.2019. Fee paid Rs. 20,000/-		

		vide Slip No. 0826907 dated 05-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	ATC Code: M01AB05 Form-5
	Type of Form Finished product Specification	USP Specifications.
	Pack size & Demanded Price	10's, 20's, 100's. As per SRO.
	Approval status of product in	•
	Reference Regulatory Authorities	Could not be verified.
	Me-too status	Voltral 100mg SR Tablets Reg. No. 021526
	CL CD	M/s Novartis Pharma Karachi.
	GMP status	Last inspection conducted on 08.06.2022. GMP status is good.
	Remarks of the Evaluator	Evidence of product approval in RRA is required.
		oval of applied formulation in reference regulatory by the Registration Board in its 275 th meeting.
279.	Name and address of manufacturer/	M/s. Relizon Pharmaceuticals, Plot No. 118, Sundar
	Applicant	Industrial Estate, Raiwind Road, Lahore. (DML No. 000875)
		Tablet (general) Section
	Brand Name + Dosage Form +	Ebastizon 10mg Tablet
	Strength	
	Composition	Each film coated tablet contains; Ebastine10mg
	Diary No. Date of R & I & fee	Dy. No. 15500 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0760244 dated 05-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX22
	Type of Form	Form-5
	Finished product Specification	JP Specifications.
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ebastine Viatris 10mg film-coated tablet ANSM, France Approved.
	Me-too status	Mestin 10mg Tablet Reg. No. 094054
		M/s Metro Pharmaceuticals Rawat.
	GMP status	Last inspection conducted on 08.06.2022. GMP status is good.
	Remarks of the Evaluator	5 00 d .
	Decision: Duplicate with case at S. No	
280.	Name and address of manufacturer/ Applicant	M/s. Relizon Pharmaceuticals, Plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore. (DML No. 000875) Tablet (general) Section
	Brand Name + Dosage Form + Strength	DOMPIZON 10mg Tablet
	Composition	Each tablet contains;
	Diary No. Date of R & I & fee	Domeperidone as maleate10mg Dy. No. 15499 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0760249 dated 05-03-2019, endorsed on
		vide slip No. 0/00249 dated 03-03-2019, endorsed on

		Tablet (general) Section
282.	Name and address of manufacturer/ Applicant	M/s. Relizon Pharmaceuticals, Plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore. (DML No. 000875)
282	 alongwith registration number, brand Reference of finished product spec 	ifications
	Decision: Deferred for following:	·
		required. • Evidence of approval of applied formulation in RRA of is required
	Remarks of the Evaluator	good. • Reference of finished product specifications is
	GMP status	Last inspection conducted on 08.06.2022. GMP status is
	Me-too status	Straza Tablet Reg. No. 096316 M/s Asian Continental Karachi.
	Approval status of product in Reference Regulatory Authorities	Applied product is not effervescent. BREXIN 20 MG EFFERVESCENT TABLET ANSM FRANCE APPROVED.
	Pack size & Demanded Price	As per SRO.
	Finished product Specification	Not mentioned.
	Type of Form	ATC Code: M01AC01 Form-5
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Oxicams
	Diary No. Date of R & I & fee	Dy. No. 15504 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0826913 dated 05-03-2019, endorsed on 07.03.2019.
	Composition	Each tablet contains; Piroxicam beta cyclodextrin equivalent to Piroxicam20mg
	Brand Name + Dosage Form + Strength	PIRON 20mg Tablet
		000875) Tablet (general) Section
281.	Name and address of manufacturer/ Applicant	M/s. Relizon Pharmaceuticals, Plot No. 118, Sundar Industrial Estate, Raiwind Road, Lahore. (DML No.
	Decision: Approved	
	Remarks of the Evaluator	good.
	GMP status	Last inspection conducted on 08.06.2022. GMP status is
	Me-too status	TGA Approved Domlis 10mg Tablet by M/s Lisko Pakistan (Reg#094897)
	Approval status of product in Reference Regulatory Authorities	DOMPERIDONE APOTEX domperidone (as maleate) 10mg tablets
	Pack size & Demanded Price	10's, As per SRO.
	Finished product Specification	BP Specifications.
	Type of Form	Form-5
	Filarmacological Group	ATC Code: A03FA03
	Pharmacological Group	07.03.2019. Propulsives

	Prond Name Dosage Form	Matrozon 400mg Tablet
	Brand Name + Dosage Form + Strength	Metrozon 400mg Tablet
	Composition	Each film coated tablet contains;
	Composition	Metronidazole400mg
	Diary No. Date of R & I & fee	Dy. No. 15501 dated 07.03.2019. Fee paid Rs. 20,000/-
	Diary No. Date of R & I & Ice	vide Slip No. 0760246 dated 05-03-2019, endorsed on
		07.03.2019.
	Pharmacological Group	Agents Against Amoebiasis And Other Protozoal
	Thurmacological Group	Diseases, Nitroimidazole Derivatives.
		ATC Code: P01AB01
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in	METRONIDAZOLE 400 MG FILM-COATED
	Reference Regulatory Authorities	TABLETS - PL 43461/0068
		MHRA Approved
	Me-too status	Flagyl Tablets 400mg Reg. No. 000827
	GMP status	Last inspection conducted on 08.06.2022. GMP status is
		good.
	Remarks of the Evaluator	
	Decision: Approved.	
283.	Name and address of manufacturer/	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder
	Applicant	Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No.
		000884)
		Tablet (general) Section
	Brand Name + Dosage Form +	Lowpress 50mg Tablet
	Strength	
	Composition	Each film coated tablet contains;
		Losartan potassium50mg
	Diary No. Date of R & I & fee	Dy. No. 17037 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0849832 dated 28-02-2019, endorsed on
		28.02.2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
		ATC Code: C09CA01
	Type of Form	Form-5
	Finished product Specification	Not mentioned. (monograph available in USP)
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in	LOSARTAN POTASSIUM 50 MG FILM-COATED
	Reference Regulatory Authorities	TABLETS
		MHRA Approved.
	Me-too status	Lo-K Tablets 50mg Reg. No. 050968
	CLED	M/s Leads Pharma islamabad.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is
	D. I. C.I. E. I.	submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	Reference of finished product specifications is
		required.
		ecifications. The firm shall submit fee of Rs. 7,500/- for
		oduct specifications as per notification No.F.7-11/2012-
	B&A/DRAP dated 07-05-2021, before issu	nance of registration fetter.

284.	Name and address of manufacturer/	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder
	Applicant	Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No.
		000884)
		Tablet (general) Section
	Brand Name + Dosage Form + Strength	ARIPIZOLE 15mg Tablet
	Composition	Each film coated tablet contains;
	Composition	Aripiprazole15mg
	Diary No. Date of R & I & fee	Dy. No. 17036 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0786687 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antipsychotics ATC Code: N05AX12
	Type of Form	Form-5
	Finished product Specification	Hi-Med's Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	
		MHRA Approved.
	Me-too status	Mactril tablet 15mg Reg. No. 067735
		M/s Wilshire Laboratories Lahore.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is
		submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	
		s specifications. The firm shall submit fee of Rs. 7,500/- for roduct specifications as per notification No.F.7-11/2012-uance of registration letter.
285.	Name and address of manufacturer/	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder
	Applicant	Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884)
		Tablet (general) Section
	Brand Name + Dosage Form + Strength	FINAMED 5mg Tablet
	Composition	Each film coated tablet contains;
	1	Finasteride5mg
	Diary No. Date of R & I & fee	Dy. No. 17032 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0832246 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Testosterone-5-alpha reductase inhibitors ATC code: G04CB01
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in	Finasteride 5mg Film-Coated Tablets - PL 21300/0019
	Reference Regulatory Authorities	MHRA Approved.
	Me-too status	Prosnom Tablet 5mg Reg. No. 024677 M/s Pharmatec Pakistan.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	

	Decision: Approved.	
286.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	FLUFEN 100mg Tablet
	Composition	Each film coated tablet contains; Flurbiprofen100mg
	Diary No. Date of R & I & fee	Dy. No. 17023 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0832247 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Propionic acid derivatives ATC Code: M01AE09
	Type of Form	Form-5
	Finished product Specification	Not mentioned (Available in BP&USP)
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Flurbiprofen 100mg Tablet Oral USFDA Approved.
	Me-too status	Ansaid 100mg Tablet Reg. No. 012299 M/s Pfizer Pakistan.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	Reference of finished product specifications is required.
	correction/pre-approval change in pr	ecifications. The firm shall submit fee of Rs. 7,500/- for roduct specifications as per notification No.F.7-11/2012-
	B&A/DRAP dated 07-05-2021, before iss	
287.	B&A/DRAP dated 07-05-2021, before iss Name and address of manufacturer/ Applicant	wance of registration letter. M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884)
287.	Name and address of manufacturer/ Applicant Brand Name + Dosage Form +	uance of registration letter. M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No.
287.	Name and address of manufacturer/ Applicant	uance of registration letter. M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section
287.	Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section RIBAMED 200mg Capsule Each capsule contains;
287.	Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section RIBAMED 200mg Capsule Each capsule contains; Ribavirin200mg Dy. No. 17028 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 081x944 dated 06-03-2019, endorsed on
287.	Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section RIBAMED 200mg Capsule Each capsule contains; Ribavirin200mg Dy. No. 17028 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 081x944 dated 06-03-2019, endorsed on 06.03.2019. Antivirals for treatment of HCV infections
287.	Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section RIBAMED 200mg Capsule Each capsule contains; Ribavirin200mg Dy. No. 17028 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 081x944 dated 06-03-2019, endorsed on 06.03.2019. Antivirals for treatment of HCV infections ATC Code: J05AP01
287.	Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section RIBAMED 200mg Capsule Each capsule contains; Ribavirin200mg Dy. No. 17028 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 081x944 dated 06-03-2019, endorsed on 06.03.2019. Antivirals for treatment of HCV infections ATC Code: J05AP01 Form-5 USP Specifications
287.	Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section RIBAMED 200mg Capsule Each capsule contains; Ribavirin200mg Dy. No. 17028 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 081x944 dated 06-03-2019, endorsed on 06.03.2019. Antivirals for treatment of HCV infections ATC Code: J05AP01 Form-5 USP Specifications As per SRO. Ribavirin 200 mg capsules, hard
287.	Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section RIBAMED 200mg Capsule Each capsule contains; Ribavirin200mg Dy. No. 17028 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 081x944 dated 06-03-2019, endorsed on 06.03.2019. Antivirals for treatment of HCV infections ATC Code: J05AP01 Form-5 USP Specifications As per SRO.
287.	Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section RIBAMED 200mg Capsule Each capsule contains; Ribavirin200mg Dy. No. 17028 dated 07.03.2019. Fee paid Rs. 20,000/vide Slip No. 081x944 dated 06-03-2019, endorsed on 06.03.2019. Antivirals for treatment of HCV infections ATC Code: J05AP01 Form-5 USP Specifications As per SRO. Ribavirin 200 mg capsules, hard MHRA Approved. Anti-C cap 200mg Reg. No. 029547 M/s Werrick Islamabad. GMP certificate dated 27.06.2022 valid till 09.06.2024 is
287.	Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No 000884) Capsule (general) Section RIBAMED 200mg Capsule Each capsule contains; Ribavirin200mg Dy. No. 17028 dated 07.03.2019. Fee paid Rs. 20,000/vide Slip No. 081x944 dated 06-03-2019, endorsed or 06.03.2019. Antivirals for treatment of HCV infections ATC Code: J05AP01 Form-5 USP Specifications As per SRO. Ribavirin 200 mg capsules, hard MHRA Approved. Anti-C cap 200mg Reg. No. 029547 M/s Werrick Islamabad.

	Decision: Approved.	
288.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	MELOCAM 7.5mg Chewable Tablet
	Composition	Each chewable tablet contains; Meloxicam7.5mg
	Diary No. Date of R & I & fee	Dy. No. 17054 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0849822 dated 27-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	Oxicams ATC code: M01AC06
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified for chewable tablet.
	Me-too status	Could not be verified for chewable.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	Reference of finished product specifications is required. Friday and product specifications of specifications is required.
		• Evidence of me-too and evidence of approval of applied formulation (chewable) in RRA is required.
	 Deferred for following: Reference of finished product spec Evidence of approval of applied formudeclared/approved by the Registratio 	ılation in reference regulatory authorities/agencies which were
289.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	MELOCAM 15mg Chewable Tablet
	Composition	Each chewable tablet contains; Meloxicam15mg
	Diary No. Date of R & I & fee	Dy. No. 17055 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0849823 dated 27-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	Oxicams ATC code: M01AC06
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified for chewable tablet.
	Me-too status	Could not be verified for chewable.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.

Remarks of the Evaluator Reference of finished product required. Evidence of me-too and evid applied formulation (chewable) Reference of finished product specifications. Reference of approval of applied formulation in reference regulatory authorities declared/approved by the Registration Board. Name and address of manufacturer/ Applicant M/s. Hi-Med Pharmaceuticals (Pvt.) Industrial estate (P.I.E.) Raiwind Road 000884) Tablet (general) Section Brand Name + Dosage Form + MELOCAM 7.5mg Tablet	dence of approval of e) in RRA is required. es/agencies which were 1) Itd., 208-C Sunder
 Reference of finished product specifications. Evidence of approval of applied formulation in reference regulatory authoritie declared/approved by the Registration Board. Name and address of manufacturer/ Applicant) ltd., 208-C Sunder
Applicant Industrial estate (P.I.E.) Raiwind Road 000884) Tablet (general) Section	
Brand Name + Dosage Form + MELOCAM 7.5mg Tablet	
Strength	
Composition Each film coated tablet contains; Meloxicam7.5mg	
Diary No. Date of R & I & fee Dy. No. 17052 dated 07.03.2019. For vide Slip No. 0849830 dated 27-02 28.02.2019.	•
Pharmacological Group Oxicams ATC code: M01AC06	
Type of Form Form-5	
Finished product Specification Not mentioned (Available in	n BP & USP)
Pack size & Demanded Price As per SRO.	,
Approval status of product in MELOXICAM 7.5 MG TABLETS - Reference Regulatory Authorities MHRA Approved.	PL 14251/0097
Me-too status Xobix 7.5mg Tablet Reg. No. 023928 M/s Hilton Pharma Karachi.	3
GMP status GMP certificate dated 27.06.2022 va submitted. Last inspection conducted	
Remarks of the Evaluator Reference of finished production required. The innovator product is unconformulation is of coated table with fee of Rs. 7500/- is required.	ated, whereas applied let. Correction along
Decision: Approved with USP Specifications and following label; "Each tablet contains; Meloxicam7.5mg" The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in prod description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 registration letter.	luct specifications and
Name and address of manufacturer/ Applicant M/s. Hi-Med Pharmaceuticals (Pvt.) Industrial estate (P.I.E.) Raiwind Road 000884) Tablet (general) Section	
Brand Name + Dosage Form + MELOCAM 15mg Tablet Strength	
Composition Each film coated tablet contains; Meloxicam15mg	
Diary No. Date of R & I & fee Dy. No. 17053 dated 07.03.2019. For vide Slip No. 0849829 dated 27-02 28.02.2019.	•
Pharmacological Group Oxicams	

		ATC code: M01AC06	
	Type of Form	Form-5	
	Finished product Specification	Not mentioned (Available in BP & USP)	
	Pack size & Demanded Price	As per SRO.	
	Approval status of product in	Meloxicam 15mg Tablets	
	Reference Regulatory Authorities	MHRA Approved.	
	Me-too status	Xobix 15mg Tablet Reg. No. 023929	
		M/s Hilton Pharma Karachi.	
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.	
	Remarks of the Evaluator	 Reference of finished product specifications is required. 	
		The innovator product is uncoated, whereas applied	
		formulation is of coated tablet. Correction along	
		with fee of Rs. 7500/- is required.	
	Decision: Approved with USP Specific		
	"Each tablet contains;	Ç	
	Meloxicam15mg"		
	· ·	r correction/pre-approval change in product specifications -11/2012-B&A/DRAP dated 07-05-2021, before issuance of	
292.	Name and address of manufacturer/	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder	
	Applicant	Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No.	
		000884)	
		Capsule (general) Section	
	Brand Name + Dosage Form + Strength	PREGAB 50mg Capsule	
	Composition	Each capsule contains;	
	-	Pregabalin50mg	
	Diary No. Date of R & I & fee	Dy. No. 17049 dated 07.03.2019. Fee paid Rs. 20,000/-	
		vide Slip No. 0832249 dated 06-03-2019, endorsed on	
		06.03.2019.	
	Pharmacological Group	Other antiepileptics	
		ATC Code: N03AX16	
	Type of Form	Form-5	
	Finished product Specification	Innovator Specifications	
	Pack size & Demanded Price	14's. As per SRO.	
	Approval status of product in	Lyrica® 50 mg hard capsules	
	Reference Regulatory Authorities	MHRA Approved.	
	Me-too status	Gabica 50 mg Capsule Reg. No. 048725	
		M/s Getz Pharma (Pvt) Ltd Karachi	
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is	
		submitted. Last inspection conducted on 10.06.2022.	
	Remarks of the Evaluator		
	Decision: Approved with BP Specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.		
293.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section	
L		Caponio (Soliciai) Doction	

	Brand Name + Dosage Form + Strength	PREGAB 75mg Capsule
	Composition	Each capsule contains; Pregabalin75mg
	Diary No. Date of R & I & fee	Dy. No. 17056 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0832243 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of Form	Form-5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Pregabalin Noumed 25, 50, 75, 100, 150, 200, 225 and 300mg Capsules, hard (pregabalin) - PL 44041/0065-0072 MHRA Approved.
	Me-too status	Gabica 75 mg Capsule Reg. No. 047365
		M/s Getz Pharma (Pvt) Ltd Karachi
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is
		submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	
	per notification No.F.7-11/2012-B&A/DR	or correction/pre-approval change in product specifications as AP dated 07-05-2021, before issuance of registration letter.
294.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section
	Brand Name + Dosage Form + Strength	PREGAB 300mg Capsule
	Composition	Each capsule contains; Pregabalin300mg
	Diary No. Date of R & I & fee	Dy. No. 17051 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0832242 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of Form	Form-5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Pregabalin Noumed 25, 50, 75, 100, 150, 200, 225 and 300mg Capsules, hard (pregabalin) - PL 44041/0065-0072 MHRA Approved.
	Me-too status	Gabica 300 mg Capsule Reg. No. 047368 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifica	tions.

		or correction/pre-approval change in product specifications as AP dated 07-05-2021, before issuance of registration letter.	
295.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section	
	Brand Name + Dosage Form + Strength	Levomed 5mg tablet	
	Composition	Each film coated tablet contains; Levocetrizine5mg	
	Diary No. Date of R & I & fee	Dy. No. 170410 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0786694 dated 06-03-2019, endorsed on 06.03.2019.	
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE, Piperazine derivatives. ATC Code: R06AE09	
	Type of Form	Form-5	
	Finished product Specification	Not mentioned (available in USP)	
	Pack size & Demanded Price	14's. As per SRO.	
	Approval status of product in Reference Regulatory Authorities		
	Me-too status	T-Day Tablet 5 mg Reg. No. 083964 M/s GlaxoSmithKline Petaro Roard.	
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.	
	Remarks of the Evaluator	 Reference of finished product specifications is required. Label claim does not mention dihydrochloride salt. Revision as per innovator product along with full fee (i.e. Rs.30,000/-) is required. 	
	Decision: Approved with USP Specific	cations and following label;	
	"Each film coated tablet cont	,	
	Levocetrizine as dihydrochlo	8	
	The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.		
296.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884)	
	Brand Name + Dosage Form + Strength	Tablet (general) Section Levomed 10mg tablet	
	Composition	Each film coated tablet contains; Levocetrizine10mg	
	Diary No. Date of R & I & fee	Dy. No. 17046 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0786695 dated 06-03-2019, endorsed on 06.03.2019.	
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE, Piperazine derivatives. ATC Code: R06AE09	
	Type of Form	Form-5	
	Finished product Specification	Not mentioned (available in USP)	
	Pack size & Demanded Price	14's. As per SRO.	
		` ,	

	Approval status of product in	Could not be verified for 10mg strength
	Reference Regulatory Authorities	
	Me-too status	L-Citriza 10mg Tablets Reg. No. 080407
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is
		submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	 Reference of finished product specifications is required.
		Evidence of approval of applied formulation in
	Designary Defended for following.	RRA is required.
	Decision: Deferred for following:Reference of finished product spec	eifications.
		ulation in reference regulatory authorities/agencies which were
297.	Name and address of manufacturer/	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder
	Applicant	Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884)
		Tablet (general) Section
	Brand Name + Dosage Form + Strength	Levamed 250mg tablet
	Composition	Each film coated tablet contains; Levetiracetam250mg
	Diary No. Date of R & I & fee	Dy. No. 17047 dated 07.03.2019. Fee paid Rs. 20,000/-
	Diary No. Date of R & I & Iee	vide Slip No. 0786698 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX14
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in	LEVETIRACETAM RIVOPHARM 250 MG FILM-
	Reference Regulatory Authorities	COATED TABLETS - PL 33155/0025
	Reference Regulatory Authorities	MHRA Approved.
	Me-too status	Vicet Tablet 250mg Re. No. 061773
	Me-too status	M/s Martin Dow Ltd. Karachi.
	CMD states	GMP certificate dated 27.06.2022 valid till 09.06.2024 is
	GMP status	submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	submittee. East inspection conducted on 10.00.2022.
	Decision: Approved.	
298.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884)
		Tablet (general) Section
	Brand Name + Dosage Form + Strength	Levamed 500mg tablet
	Composition	Each film coated tablet contains; Levetiracetam500mg
	Diary No. Date of R & I & fee	Dy. No. 17048 dated 07.03.2019. Fee paid Rs. 20,000/vide Slip No. 0786699 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX14

	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in	LEVETIRACETAM RIVOPHARM 500 MG FILM-
	Reference Regulatory Authorities	COATED TABLETS - PL 33155/0026
		MHRA Approved.
	Me-too status	Vicet Tablet 500mg Re. No. 061774
		M/s Martin Dow Ltd. Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is
		submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	
	Decision: Approved.	
	Name and address of manufacturer/	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunde
	Applicant	Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No
		000884)
		Tablet (general) Section
	Brand Name + Dosage Form +	DOMMED 10mg Tablet
	Strength	
	Composition	Each film coated tablet contains;
		Domeperidone maleate 12.72 mg eq to
		domeperidone10mg
	Diary No. Date of R & I & fee	Dy. No. 17038 dated 07.03.2019. Fee paid Rs. 20,000
		vide Slip No. 0786693 dated 06-03-2019, endorsed o
		06.03.2019.
	Pharmacological Group	Propulsives
		ATC code: A03FA03
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in	DOMPERIDONE ARROW 10 mg film-coated tablet
	Reference Regulatory Authorities	ANSM France approved
		Domperidone 10 mg Tablets (uncoated)
		Each tablet contains 12.72 mg of Domperidone maleate
		equivalent to 10 mg Domperidone
		MhRA Approved.
	Me-too status	Motilium Tablet 10mg (Domeperidone HCl 10mg) Reg
		No. 006526
		M/s Aspin Pharma (Pvt.) ltd. Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 i
		submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	The product approved by ANSM France does not
		mention maleate salt, whereas product approved i
		MHRA is uncoated. Further, me-too is approved a
		HCl salt.
		Reference of finished product specifications is
		required.

- Reference of finished product specifications.
- Revision of formulation as per innovator product along with submission of requisite fee.

300.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884)	
		Tablet (general) Section	
	Brand Name + Dosage Form + Strength	BHIS 16mg Tablet	
	Composition	Each Film coated tablet contains; Betahistine16mg	
	Diary No. Date of R & I & fee	Dy. No. 17038 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0849824 dated 28-02-2019, endorsed on 28.02.2019.	
	Pharmacological Group	ANTIVERTIGO PREPARATIONS ATC Code: N07CA01	
	Type of Form	Form-5	
	Finished product Specification	Not mentioned	
	Pack size & Demanded Price	As per SRO.	
	Approval status of product in Reference Regulatory Authorities	BETAHISTINE DIHYDROCHLORIDE DAWA 16MG TABLETS 16 MG TABLETS - PL 30684/0298 MHRA Approved	
	Me-too status	BHS Tablet 16mg, Rotex Pharma, Reg. No. 100819	
	GMP status Remarks of the Evaluator	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.	
		 Reference of finished product specifications is required. The product approved in RRA is uncoated whereas applied formulation is of coated product. Clarification or correction is required. The innovator uses dihydrochloride salt whereas in applied formulation base is used. Justification or correction along with fee of Rs. 30,000/- is required. 	
	Decision: Approved with innovator's Each tablet contains; Betahistine dihydrochloride.	16mg	
	The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.		
301.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section	
	Brand Name + Dosage Form + Strength	LOPRIDON 2mg Tablet	
	Composition	Each film coated tablet contains; Iloperidone2mg	
	Diary No. Date of R & I & fee	Dy. No. 17043 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0849825 dated 28-02-2019, endorsed on 28.02.2019.	
	Pharmacological Group	Other antipsychotics ATC Code: N05AX14	
	Type of Form	Form-5	
	Finished product Specification	Not mentioned	
	Pack size & Demanded Price	As per SRO.	

	Approval status of product in	FANAPT (iloperidone 1mg, 2mg, 4mg, 6mg, 8mg, 10mg,
	Reference Regulatory Authorities	12mg) uncoated Tablets
	Telefolie Regulatory Flathornes	USFDA Approved.
	Me-too status	Ereden 2mg Tablet Reg. No. 083307
	Mc-too status	M/s Martin Dow Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is
	GWF status	
	Demonto of the Evoluctor	submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	 Reference of finished product specifications is required.
		The product approved in RRA is uncoated whereas
		applied formulation is of coated product.
		Clarification or correction is required along with fee
		of Rs. 7500/-
	Decision: Approved with innovator's	
	Each tablet contains;	
	Iloperidone2mg	
		or correction/pre-approval change in product specifications 7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of
302.	Name and address of manufacturer/	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder
302.	Applicant	Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No.
	Applicant	000884)
	Duon d Nomes Dossess Forms	Tablet (general) Section
	Brand Name + Dosage Form + Strength	LOPRIDON 4mg Tablet
	Composition	Each film coated tablet contains;
		Iloperidone4mg
	Diary No. Date of R & I & fee	Dy. No. 17044 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 1900220 dated 06-03-2019, endorsed on
		06.03.2019.
	Pharmacological Group	Other antipsychotics
		ATC Code: N05AX14
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in	FANAPT (iloperidone 1mg, 2mg, 4mg, 6mg, 8mg, 10mg,
	Reference Regulatory Authorities	12mg) uncoated Tablets
	Therefore Regulatory Transferres	USFDA Approved.
	Me-too status	Ereden 4mg Tablet Reg. No. 083306
	THE too status	M/s Martin Dow Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is
	GMT Status	submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	Reference of finished product specifications is
		required.
		The product approved in RRA is uncoated whereas
		applied formulation is of coated product.
		Clarification or correction is required along with fee
	Decisions Ammuovad	of Rs. 7500/-
	Decision: Approved with innovator's	specifications and following label;
	Each tablet contains;	
	Iloperidone4mg	

		or correction/pre-approval change in product specifications V-11/2012-B&A/DRAP dated 07-05-2021, before issuance of
303.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	Sparomed 100mg Tablet
	Composition	Each film coated tablet contains; Sparfloxacin100mg
	Diary No. Date of R & I & fee	Dy. No. 17030 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0849831 dated 28-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA09
İ	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Spar-Cin 100mg Tablet Reg. No. 036762 M/s Fozan Pharmaceuticals Peshawar.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	 Reference of finished product specifications is required. Evidence of approval of applied formulation in
	Decision: Deferred for following:	RRA is required.
	• Reference of finished product s	specifications
		formulation in reference regulatory authorities/agencies which
304.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	OSAMED 830mg Tablet
	Composition	Each film coated tablet contains; Ossein mineral complex830mg
	Diary No. Date of R & I & fee	Dy. No. 17042 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0786692 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Calcium and multimineral
	Type of Form	Form-5
	Finished product Specification	Not Mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status	Osteoget Tablet Reg. No. 063417 M/s Global Pharma Islamabad.

	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is
	Remarks of the Evaluator	 submitted. Last inspection conducted on 10.06.2022. Reference of finished product specifications is
		required.
		Evidence of approval of applied formulation in DRA is required.
	Decision: Deferred for following:	RRA is required.
	Reference of finished product s	specifications.
	 Evidence of of approval of appl which were adopted by the Regist 	ied formulation in reference regulatory authorities/agencies
305.	Name and address of manufacturer/	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder
	Applicant	Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884)
		Tablet (general) Section
	Brand Name + Dosage Form + Strength	FEXOMED 60mg/120mg Tablet
	Composition	Each film coated tablet contains;
		Fexofenadine HCl60mg
	Di N. D. CD 0 I 0 C	Pseudoephedrine HCl120mg
	Diary No. Date of R & I & fee	Dy. No. 17025 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0849833 dated 28-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	pseudoephedrine, combinations
		ATC Code: R01BA52
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	ALLEGRA-D Fexofenadine hydrochloride and pseudoephedrine hydrochloride caplets (Sustained-
	Reference Regulatory Authorities	Release) Caplets, 60 mg & 120 mg, Oral.
		The product approved by Health Canada is a Sustained
		release formulation.
	Me-too status	Fexo-D Tablets Reg. No. 031607
		M/s Hilton Pharma (Pvt.) Ltd.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is
		submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	Evidence of approval of applied formulation in Output Description:
	Decision: Deferred evidence of app	RRA is required. oroval of applied formulation in reference regulatory
	authorities/agencies which were declared/approved by the Registration Board.	
306.	Name and address of manufacturer/	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder
	Applicant	Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No.
		000884)
	Drand Name + Degage Form	Tablet (general) Section
	Brand Name + Dosage Form + Strength	HISARTAN 80mg Tablet
	Composition	Each film coated tablet contains;
		Valsartan80mg
	Diary No. Date of R & I & fee	Dy. No. 17040 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0849819 dated 28-02-2019, endorsed on
		28.02.2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain

		ATC Code: C09CA03
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	VALSARTAN 80 MG FILM-COATED TABLETS 80 MG FILM-COATED TABLET - PL 08553/0700 MHRA Approved.
	Me-too status	Valbar 80mg Tablet Reg. No. 086702 M/s Barrett Hodgson Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	Reference of finished product specifications is required.
		ifications. The firm shall submit fee of Rs. 7,500/- for oduct specifications as per notification No.F.7-11/2012-
307.	Name and address of manufacturer/	
307.	Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	AMVAL Plus 10mg Tablet
	Composition	Each film coated tablet contains; Amlodipine (as besylate)5mg Valsartan160mg
	Diary No. Date of R & I & fee	Dy. No. 17040 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0849819 dated 28-02-2019, endorsed on 28.02.2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers ATC Code: C09DB01
	Type of Form	Form-5
	Finished product Specification	Hi MED Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan Kappler 5 mg/80 mg, 5 mg/160 mg and 10 mg/160 mg film-coated tablets - PL 22363/0023-0025; UK/H/6785/001-003/DC MHRA Approved.
	Me-too status	Extor 5mg+160mg Reg. No. 054502 M/s Searle company Ltd. Lahore.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	 Reference of finished product specifications is required.
		ifications. The firm shall submit fee of Rs. 7,500/- for oduct specifications as per notification No.F.7-11/2012-nance of registration letter.
308.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884)
		Tablet (general) Section

	Brand Name + Dosage Form + Strength	AMPRIDE 50mg Tablet
	Composition	Each film coated tablet contains; Amisulpride50mg
	Diary No. Date of R & I & fee	Dy. No. 17021 dated 07.03.2019. Fee paid Rs. 20,000/vide Slip No. 0786686 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	ANTIPSYCHOTICS, Benzamides ATC Code: N05AL05
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Amisulpride 50mg Tablets - PL 04416/0592 MHRA Approved.
	Me-too status	Amis 50mg Tablet Reg. No. 064017 M/s Genome Pharma Haripur
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	Reference of finished product specifications is required.
		The product approved in RRA is uncoated whereas applied formulation is of coated product. Clarification or correction is required along with fee
	Decision: Approved with BP specifica	of Rs. 7500/-
	Each tablet contains; Amisulpride50mg The firm shall submit fee of Rs. 7,500/- for	,
309.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form +	GLIMED 2mg Tablet
	Strength	GENVIED Zing Tablet
	Composition	Each film coated tablet contains; Glimepiride2mg
	Diary No. Date of R & I & fee	Dy. No. 17033 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0786690 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Oral blood glucose lowering drugs: Sulfonamides, urea derivatives. ATC Code: A10BB12
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Glimepiride 2 mg Tablets MHRA Approved.
	Me-too status	Amaryl tab 2 mg Reg. No. 019568
	142 too status	M/s Sanofi-Aventis Pakistan Ltd. Plot No. 23, Sector 22 Korangi Industrial Area Karachi.

	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is	
	Remarks of the Evaluator	submitted. Last inspection conducted on 10.06.2022. • Reference of finished product specifications is	
	Remarks of the Evaluator	 Reference of finished product specifications is required. The product approved in RRA is uncoated whereas applied formulation is of coated product. Clarification or correction is required along with fee of Rs. 7500/- 	
		eations and following label; or correction/pre-approval change in product specifications 7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of	
310.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section	
	Brand Name + Dosage Form + Strength	MEFLOQUEN 250mg Tablet	
	Composition	Each film coated tablet contains; Mefloquine250mg	
	Diary No. Date of R & I & fee	Dy. No. 17024 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0786691 dated 06-03-2019, endorsed on 06.03.2019.	
	Pharmacological Group	Methanolquinolines ATC Code: P01BC02	
	Type of Form	Form-5	
	Finished product Specification	Not mentioned	
	Pack size & Demanded Price	As per SRO.	
	Approval status of product in Reference Regulatory Authorities	MEFLOQUINE 250 MG TABLETS, LARIAM 250MG TABLETS MHRA Approved.	
	Me-too status	Malarium 250mg Tablets Reg. No. 066319 M/s Global Pharma Islamabad	
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.	
	Remarks of the Evaluator	 Reference of finished product specifications is required. The product approved in RRA is uncoated whereas applied formulation is of coated product. Clarification or correction is required The innovator uses HCl salt, whereas applied label is of base only. Correction along with full fee i.e. Rs. 30,000/- is required. 	
	Decision: Approved with USP specifications and following label; Each tablet contains;		
	Mefloquine as hydrochloride250mg The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as		
211	· -	AP dated 07-05-2021, before issuance of registration letter.	
311.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884)	

		Tablet (general) Section
	Brand Name + Dosage Form + Strength	MITRA 30mg Tablet
	Composition	Each film coated tablet contains; Mirtazapine30mg
	Diary No. Date of R & I & fee	Dy. No. 17022 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0810944 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antidepressants ATC code: N06AX11
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Mirtazapine 15 mg, 30 mg and 45 mg film-coated tablets - PL 28444/0097-9 MHRA Approved.
	Me-too status	Tazemir 15mg Tablet Reg. No. 058172 M/s Lisko Pakistan Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	Reference of finished product specifications is required.
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
312.	Name and address of manufacturer/	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder
	Applicant	Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884)
	D 111 D 5	Tablet (general) Section
	Brand Name + Dosage Form + Strength	ONDAMED 8mg Tablet
	Composition	Each film coated tablet contains;
	Diary No. Date of R & I & fee	Ondansetron as hydrochloride dehydrate4mg Dy. No. 17041 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0786696 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS, Serotonin (5HT3) antagonists. ATC Code: A04AA01
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ondansetron 4 mg & 8 mg (Ondansetron Hydrochloride dihydrate) MHRA Approved.
	Me-too status	Zofran Tablets 4 mg Reg. No. 020667 M/s GSK Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• Covering letter and fee is submitted for 8mg strength. Form-5 is submitted for 4mg strength. Correction along with full fee is required.

	Decision: Deferred for submission of	Form-5 and complete details of 8mg strength.
313.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Tablet (general) Section
	Brand Name + Dosage Form + Strength	OLANODON 10mg Tablet
	Composition	Each film coated tablet contains; Olanzapine10mg
	Diary No. Date of R & I & fee	Dy. No. 17039 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0786689 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH03
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Olanzapine 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg and 20 mg Tablets - PL 32854/0015-20 (Zyprexa coated) MHRA Approved.
	Me-too status	Olanzia Tablets 10mg Reg. no. 054721 M/s Werrick Pharma Islamabad.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	 Reference of finished product specifications is required.
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
314.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section
	Brand Name + Dosage Form + Strength	ACIMED 10mg Capsule
	Composition	Each Capsule contains; Acitretin10mg
	Diary No. Date of R & I & fee	Dy. No. 17031 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0786688 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Retinoids for treatment of psoriasis ATC Code: D05BB02
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Acitretin 10 mg and 25 mg Capsules - PL 20117/0265-6 MHRA Approved.
	Me-too status	ACT 10mg Capsule Reg. No. 081575 M/s Ciba Pharmaceuticals Jamshoro
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.

	Remarks of the Evaluator	• Reference of finished product specifications is required.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.		
315.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section	
	Brand Name + Dosage Form + Strength	MEBMED 200mg Capsule	
	Composition	Each Capsule contains; Mebeverine hydrochloride (SR pellets 50%) 200mg Source: Vision Pharma	
	Diary No. Date of R & I & fee	Dy. No. 17026 dated 07.03.2019. Fee paid Rs. 20,000/vide Slip No. 0786700 dated 06-03-2019, endorsed on 06.03.2019.	
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group ATC Code: A03AA04	
	Type of Form	Form-5	
	Finished product Specification	Manufacturers Specification's	
	Pack size & Demanded Price	10's. As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Mebeverine 200 mg modified release capsules (mebeverine hydrochloride) - PL 35533/0095 MHRA Approved.	
	Me-too status	Mebever MR 200mg Capsule Reg. No. 050747 M/s Getz Pharma Karachi.	
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is submitted. Last inspection conducted on 10.06.2022.	
	Remarks of the Evaluator		
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.		
316.	Name and address of manufacturer/ Applicant	M/s. Hi-Med Pharmaceuticals (Pvt.) ltd., 208-C Sunder Industrial estate (P.I.E.) Raiwind Road, Lahore. (DML No. 000884) Capsule (general) Section	
	Brand Name + Dosage Form + Strength	HImed 120mg Capsule	
	Composition	Each Capsule contains; Orlistat (uncoated pellets 50%)120mg Source: M/s Vision Pharmaceuticals.	
	Diary No. Date of R & I & fee	Dy. No. 17027 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0832248 dated 06-03-2019, endorsed on 06.03.2019.	
	Pharmacological Group	Peripherally acting antiobesity products ATC Code: A08AB01	
	Type of Form	Form-5	
	Finished product Specification	USP Specifications	

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	Approval status of product in	Orlistat 120 mg hard capsules (orlistat) - PL 20416/0270
	Reference Regulatory Authorities	MHRA Approved.
	Me-too status	OSKER 120mg Capsules Reg. No. 066788
		M/s Genix Pharma Karachi.
	GMP status	GMP certificate dated 27.06.2022 valid till 09.06.2024 is
		submitted. Last inspection conducted on 10.06.2022.
	Remarks of the Evaluator	• The label claim on Form-5 is incorrect. Revised
		Form-5 along with full fee is required.
		• Real time and accelerated stability study data of 3
		batches of pellets is required.
	Decision: Deferred for following;	
	<u> </u>	along with fee of Rs. 30,000/- as per SRO496(I)/2023
	Real time and accelerated stability	ility data of 3 hatches of nellets.
317.	Name and address of manufacturer/	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road,
317.	Applicant	Layyah. (DML No. 000774)
	Applicant	,
	Drond Nome + December 1	Tablet (general) Section
	Brand Name + Dosage Form +	EPAX-M 5mg+1000mg Tablet
	Strength	Fort Claraca and total and contains
	Composition	Each film coated tablet contains;
		Empagliflozin5mg
		Metformin hydrochloride USP1000mg
	Diary No. Date of R & I & fee	Dy. No. 15009 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0826709 dated 06-03-2019, endorsed on
		07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
		ATC Code: A10BD20
	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in	SYNJARDY 5 MG/1000 MG FILM-COATED
	Reference Regulatory Authorities	TABLETS
		MHRA Approved.
	Me-too status	Diampa-M Tablet 5mg+1000mg Reg. No. 103094
	TVIC too status	M/s Getz Pharma (Pvt) Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is
	Givii status	ok.
	Remarks of the Evaluator	
	Decision:	
210		N/ DI
318.	Name and address of manufacturer/	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road,
	Applicant	Layyah. (DML No. 000774)
		Tablet (general) Section
	Brand Name + Dosage Form +	EPAX-M 5mg+500mg Tablet
	Strength	
	Composition	Each film coated tablet contains;
		Empagliflozin5mg
		Metformin hydrochloride USP500mg
	Diary No. Date of R & I & fee	Dy. No. 15013 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0826712 dated 06-03-2019, endorsed on
		07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
		ATC Code: A10BD20
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	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in	Synjardy Empagliflozin; Metformin HCl 5mg;500mg
	Reference Regulatory Authorities	Tablet
		USFDA Approved.
	Me-too status	Diampa-M Tablet 5mg+500mg Reg. No. 105287
		M/s Getz Pharma (Pvt) Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is
		ok.
	Remarks of the Evaluator	
		tability study data as per the guidelines approved in 293 rd
	meeting of Registration Board.	
319.	Name and address of manufacturer/	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road,
	Applicant	Layyah. (DML No. 000774)
		Tablet (general) Section
	Brand Name + Dosage Form +	EPAX-M 12.5mg+850mg Tablet
	Strength	
	Composition	Each film coated tablet contains;
		Empagliflozin12.5mg
		Metformin hydrochloride USP850mg
	Diary No. Date of R & I & fee	Dy. No. 15011 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0742696 dated 06-03-2019, endorsed on
		07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
		ATC Code: A10BD20
	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in	SYNJARDY 12.5 MG/850 MG FILM-COATED
	Reference Regulatory Authorities	TABLETS
		MHRA Approved.
	Me-too status	Diampa-M Tablet 12.5mg+850mg Reg. No. 105552
		M/s Getz Pharma (Pvt) Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is
		ok.
	Remarks of the Evaluator	
		bility study data as per the guidelines approved in 293 rd
	meeting of Registration Board.	
320.	Name and address of manufacturer/	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road,
	Applicant	Layyah. (DML No. 000774)
		Tablet (general) Section
	Brand Name + Dosage Form +	EPAX-M 5mg+850mg Tablet
	Strength	
	Composition	Each film coated tablet contains;
		Empagliflozin5mg
		Metformin hydrochloride USP850mg
	Diary No. Date of R & I & fee	Dy. No. 15011 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0742696 dated 06-03-2019, endorsed on
		07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
		ATC Code: A10BD20

	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in	SYNJARDY 5 MG/850 MG FILM-COATED TABLETS
	Reference Regulatory Authorities	MHRA Approved.
	Me-too status	Diampa-M Tablet 5mg+850mg Reg. No. 103093
		M/s Getz Pharma (Pvt) Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is
		ok.
	Remarks of the Evaluator	
		ability study data as per the data requirements approved in
221	293 rd meeting of Registration Board.	M/- Dhama Land (Dat) Ltd. 12 VM Laham Dand
321.	Name and address of manufacturer/	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road,
	Applicant	Layyah. (DML No. 000774)
	Drond Name Dagge Form	Tablet (general) Section
	Brand Name + Dosage Form +	EPAX-M 12.5mg+500mg Tablet
	Strength	Each film acceed tablet contains:
	Composition	Each film coated tablet contains;
		Empagliflozin12.5mg Metformin hydrochloride USP500mg
	Diary No. Date of R & I & fee	Dy. No. 15012 dated 07.03.2019. Fee paid Rs. 20,000/-
	Diary No. Date of K & I & fee	vide Slip No. 0742695 dated 06-03-2019, endorsed on
		07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Tharmacological Group	ATC Code: A10BD20
	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in	Synjardy Empagliflozin; Metformin HCl 12.5mg;500mg
	Reference Regulatory Authorities	Tablet
	reference regulatory ruthornes	USFDA Approved.
	Me-too status	Diampa-M Tablet 12.5mg+500mg Reg. No. 105551
		M/s Getz Pharma (Pvt) Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is
		ok.
	Remarks of the Evaluator	
		bility study data as per the data requirements approved in
	293 rd meeting of Registration Board.	
322.	Name and address of manufacturer/	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road,
	Applicant	Layyah. (DML No. 000774)
		Tablet (general) Section
	Brand Name + Dosage Form +	DPAX-M 5mg+850mg Tablet
	Strength	
	Composition	Each film coated tablet contains;
		Dapagliflozin propanediol monohydrate eq. to
		Dapagliflozin5mg
	Diam No Data of D 0 I 0 C	Metformin hydrochloride USP850mg
	Diary No. Date of R & I & fee	Dy. No. 15015 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0742700 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15
<u> </u>		ATC COUC. ATODDIS

	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in	Xigduo 5 mg/850 mg film-coated tablets
	Reference Regulatory Authorities	MHRA Approved.
	Me-too status	DAPA-Met 5mg/850mg Reg. no. 093071
	112 40 0 0 0.0000	M/s Hilton Pharma Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is
	Sill status	ok.
	Remarks of the Evaluator	
	Decision: Deferred for submission of stal meeting of Registration Board.	bility study data as per the guidelines approved in 293 rd
323.	Name and address of manufacturer/	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road,
	Applicant	Layyah. (DML No. 000774)
		Tablet (general) Section
	Brand Name + Dosage Form + Strength	DPAX-M 5mg+1000mg Tablet
	Composition	Each film coated tablet contains;
		Dapagliflozin propanediol monohydrate eq. to
		Dapagliflozin5mg
		Metformin hydrochloride USP1000mg
	Diary No. Date of R & I & fee	Dy. No. 15014 dated 07.03.2019. Fee paid Rs. 20,000/-
	Blary 140. Bate of R & T & Tee	vide Slip No. 0826710 dated 06-03-2019, endorsed on
		07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD15
	Type of Form	Form-5
	Finished product Specification	Innovator Specifications.
	Pack size & Demanded Price	2x7's, 10x10's. As per SRO.
	Approval status of product in	Xigduo 5 mg/1000 mg film-coated tablets
	Reference Regulatory Authorities	MHRA Approved.
	Me-too status	DAPA-Met 5mg/1000mg Reg. no. 093072
		M/s Hilton Pharma Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is ok.
	Remarks of the Evaluator	
		bility study data as per the guidelines approved in 293 rd
	meeting of Registration Board.	
324.	Name and address of manufacturer/	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road,
	Applicant	Layyah. (DML No. 000774)
		Tablet (general) Section
	Brand Name + Dosage Form +	LERAM 250mg Tablet
	Strength	
	Composition	Each film coated tablet contains;
		Levetiracetam250mg
	Diary No. Date of R & I & fee	Dy. No. 15020 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0826713 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antiepileptics
		ATC Code: N03AX14
	Type of Form	Form-5
	Finished product Specification	USP specifications
	product appointment on	

	Pack size & Demanded Price	1x10's, 3x10's, 10x10's. As per SRO.
		· · · · · · · · · · · · · · · · · · ·
	Approval status of product in	
	Reference Regulatory Authorities	COATED TABLETS - PL 33155/0025
		MHRA Approved.
	Me-too status	Vicet Tablet 250mg Re. No. 061773
		M/s Martin Dow Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is
		ok.
	Remarks of the Evaluator	
	Decision: Approved.	
20.7	* *	
325.	Name and address of manufacturer/	M/s. Pharma Lord (Pvt.) Ltd., 12-KM Lahore Road,
	Applicant	Layyah. (DML No. 000774)
		Tablet (general) Section
	Brand Name + Dosage Form +	LERAM 500mg Tablet
	Strength	
	Composition	Each film coated tablet contains;
		Levetiracetam500mg
	Diary No. Date of R & I & fee	Dy. No. 15019 dated 07.03.2019. Fee paid Rs. 20,000/-
	Biary 110. Bate of R & T & Tee	vide Slip No. 0742699 dated 06-03-2019, endorsed on
		07.03.2019.
	Dhamma a la si a l Cuana	
	Pharmacological Group	Other antiepileptics
	m 6.5	ATC Code: N03AX14
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1x10's, 3x10's, 10x10's. As per SRO.
	Approval status of product in	LEVETIRACETAM RIVOPHARM 500 MG FILM-
	Reference Regulatory Authorities	COATED TABLETS - PL 33155/0026
		MHRA Approved.
	Me-too status	Vicet Tablet 500mg Re. No. 061774
	112 133 5.44.55	M/s Martin Dow Ltd. Karachi.
	GMP status	Last inspection conducted on 24.03.2022. GMP status is
	Givii status	ok.
	Remarks of the Evaluator	OK.
	Decision: Approved.	
326.	Name and address of manufacturer/	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33-
	Applicant	KM, Ferozupur Road, Lahore. (DML No. 000389)
		Tablet (general) Section
	Brand Name + Dosage Form +	FERPRIDE 50mg Tablet
	Strength	
	Composition	Each tablet contains;
		Levosulpiride50mg
	Diary No. Date of R & I & fee	Dy. No. 17339 dated 07.03.2019. Fee paid Rs. 20,000/-
	Diary No. Date of R & T & Ice	vide Slip No. 0839957 dated 06-03-2019, endorsed on
		07.03.2019.
	Discussion of Contract Contrac	
	Pharmacological Group	ANTIPSYCHOTICS, Benzamides,
	The same of the sa	ATC Code:N05AL07
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in	LEVOPRAID® 50 mg Tablets by TEOFARMA Srl.
	Reference Regulatory Authorities	Approved by AIFA Italy
	Me-too status	Sapride Tablet 50mg Reg. No. 049950
<u> </u>		

		M/s Standpharm Pakistan Lahore.	
	GMP status	Report of 2016 is submitted.	
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.	
	Decision: Approved. Registration letter certificate or latest GMP inspection re	er shall be issued after submission of valid GMP	
327.	Name and address of manufacturer/ Applicant	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33- KM, Ferozupur Road, Lahore. (DML No. 000389) Tablet (general) Section	
	Brand Name + Dosage Form + Strength	RELAXFER 2mg Tablet	
	Composition	Each tablet contains; Tizanidine (HCl)2mg	
	Diary No. Date of R & I & fee	Dy. No. 17343 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0797035 dated 06-03-2019, endorsed on 07.03.2019.	
	Pharmacological Group	Other centrally acting agents ATC Code: M03BX02	
	Type of Form	Form-5	
	Finished product Specification	Innovator's Specifications	
	Pack size & Demanded Price	As per SRO.	
	Approval status of product in	TIZANIDINE 2MG TABLETS	
	Reference Regulatory Authorities	MHRA Appoved.	
	Me-too status	Zodin 2mg Tablet Reg. No. 063400 M/s Bio-Labs Islamabad.	
	GMP status	Report of 2016 is submitted.	
	Remarks of the Evaluator	 Latest GMP inspection report/ certificate is required. Monograph of applied product is available in pharmacopoeia, applied specs are Innovator. Clarification or correction along with requisite fee is required. 	
	Decision: Approved with USP Specifications. Firm shall submit latest GMP inspection report conducted within last three years along with fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.		
328.	Name and address of manufacturer/ Applicant	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33- KM, Ferozupur Road, Lahore. (DML No. 000389) Tablet (general) Section	
	Brand Name + Dosage Form + Strength	Lizo 600mg Tablet	
	Composition	Each tablet contains; Linezolid600mg	
	Diary No. Date of R & I & fee	Dy. No. 17340 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0839964 dated 06-03-2019, endorsed on 07.03.2019.	
	Pharmacological Group	Other antibacterials ATC Code: J01XX08	
	Type of Form	Form-5	
	Finished product Specification	Innovator's Specifications	
	Pack size & Demanded Price	As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Linezolid 600mg Film-Coated Tablets (linezolid) - PL 20416/0517	

		MHRA approved.
	Me-too status	Linzy Tablets 600mg Reg. no. 063415
		M/s Global Pharma Islamabad.
	GMP status	Report of 2016 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
		• The product approved in RRA is film coated, applied
		product is uncoated. Correction along with requisite fee
		is required.
	Decision: Approved with following la	
	"Each film coated tablet co	·
	Linezolid 600mg"	,
		report conducted within last three years along with fee of Rs. ge in product specifications as per notification No.F.7-11/2012-uance of registration letter.
329.	Name and address of manufacturer/	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33-
	Applicant	KM, Ferozupur Road, Lahore. (DML No. 000389)
		Tablet (general) Section
	Brand Name + Dosage Form +	FEROXIB 60mg Tablet
	Strength	
	Composition	Each tablet contains;
	Total Postage	Etoricoxib60mg
	Diary No. Date of R & I & fee	Dy. No. 17338 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0839959 dated 06-03-2019, endorsed on
		07.03.2019.
	Pharmacological Group	Coxibs
	Tharmacological Gloup	ATC Code: M01AH05
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in	Etoricoxib 30 mg, 60 mg, 90 mg and 120 mg film-coated
	Reference Regulatory Authorities	tablets - PL 20416/0543-0546
	Reference Regulatory Framornies	MHRA approved.
	Me-too status	Etoria 60mg Tablet Reg. No. 080818
	We too status	M/s Hygeia Pharmaceuticals Islamabad.
	GMP status	Report of 2016 is submitted.
	Remarks of the Evaluator	1
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
330.	Name and address of manufacturer/	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33-
	Applicant	KM, Ferozupur Road, Lahore. (DML No. 000389)
		Tablet (general) Section
	Brand Name + Dosage Form + Strength	ITP-FER 50mg Tablet
	Composition	Each tablet contains; Itopride (HCl)50mg
	Diary No. Date of R & I & fee	Dy. No. 17344 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0797031 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Propulsives ATC Code: A03FA07
	Type of Form	Form-5
	Type of Form	1 TOTHI-J

	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in	Itopride hydrochloride tablet 50 mg by Shiseido
	Reference Regulatory Authorities	Pharmaceutical Co., Ltd. PMDA approved
	Me-too status	Ganaton 50mg Tablet by M/s Abbott. (Reg. # 028429)
	GMP status	Report of 2016 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		• RRA approved product uses Itopride HCl 50mg, in applied formulation 50mg base is mentioned. Further innovator product is coated applied is uncoated. Correction as per innovator product is required along with full fee.
	Decision: Approved with following lab	pel;
	Each film coated tablet con	, and the second
	Itopride HCl50mg	,
		report conducted within last three years along with fee of Rs. ge in product specifications as per notification No.F.7-11/2012-uance of registration letter.
331.	Name and address of manufacturer/	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33-
	Applicant	KM, Ferozupur Road, Lahore. (DML No. 000389)
		Tablet (general) Section
	Brand Name + Dosage Form +	VILDAFER-MET 50mg/850mg Tablet
	Strength	
	Composition	Each tablet contains;
		Vildagliptin50mg
		Metformin HC1850mg
	Diary No. Date of R & I & fee	Dy. No. 17342 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0797028 dated 06-03-2019, endorsed on
	Dhamma a ala si sal Cuana	07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs. ATC Code: A10BD08
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in	Galvumet Film Coated Tablets (50 mg vildagliptin and
	Reference Regulatory Authorities	850 mg metformin hydrochloride)
		Swissmedic Approved
	Me-too status	Vilfor 50/850mg tablet Reg. No. 106507
	CI (D	M/s Hi-Medic Pharmaceuticals (Pvt) Ltd Lahore
	GMP status	Report of 2016 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		• Innovator product is coated applied is uncoated.
		Correction as per innovator product is required along
	Decision Associated following to	with requisite fee.
	Decision: Approved with following lat	Del;
	"Each film coated tablet contains;	
	Vildagliptin50mg Metformin HCl 850mg"	
		report conducted within last three years along with fee of Rs
	Firm shall submit latest GMP inspection report conducted within last three years along with fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
332.	Name and address of manufacturer/	M/s. Ferroza International Pharmaceuticals (Pvt.) ltd. 33-
334.	Applicant	KM, Ferozupur Road, Lahore. (DML No. 000389)
	пррисан	Kivi, Polozupui Koau, Lanoie. (Divid Ivo. 000307)

		Tablet (general) Section
	Brand Name + Dosage Form + Strength	Lexolfer 2.5mg Tablet
	Composition	Each tablet contains; Letrozole2.5mg
	Diary No. Date of R & I & fee	Dy. No. 17341 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0797034 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Aromatase inhibitors ATC Code: L02BG04
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Letrozole 2.5 mg Film-coated tablets - PL 25258/0198 MHRA Approved.
	Me-too status	Femara 2.5mg Tablets Reg. No. 021129 M/s Novartis Pharma Karachi.
	GMP status	Report of 2016 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		Innovator product is coated applied is uncoated. Correction as per innovator product is required along with requisite fee.
	7,500/- for correction/pre-approval chan	report conducted within last three years along with fee of Rs. ge in product description as per notification No.F.7-11/2012-
333.	B&A/DRAP dated 07-05-2021, before issues Name and address of manufacturer/	
333.	Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586)
	D IN D E	Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	DROZOL-T Ophthalmic Solution
	Composition	Each 1ml contains; Dorzolamide HCL 22.26mg eq to Dorzolamide20mg Timolol maleate 6.85mg eq to Timolol5mg
	Diary No. Date of R & I & fee	Dy. No. 14051 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0605449 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Beta blocking agents, timolol, combinations
	Thurmucorogram Group	ATC Code: S01ED51
	Type of Form	
		ATC Code: S01ED51
	Type of Form	ATC Code: S01ED51 Form-5 Manufacturer's Specifications (available in USP, JP &
	Type of Form Finished product Specification	ATC Code: S01ED51 Form-5 Manufacturer's Specifications (available in USP, JP & BP) 5mL. As per SRO. Dorzolamide/Timolol 20 mg/ml + 5 mg/ml Eye Drops Solution - PL 00289/1130; UK/H/1505/001/DC
	Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in	ATC Code: S01ED51 Form-5 Manufacturer's Specifications (available in USP, JP & BP) 5mL. As per SRO. Dorzolamide/Timolol 20 mg/ml + 5 mg/ml Eye Drops

	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		• Specifications of finished product are mentioned as
		Manufacturer Specifications. Monograph is available in pharmacopoeia. Clarification or correction along with
		requisite fee is required.
	Decision: Approved with USP Specification	ons. Firm shall submit latest GMP inspection report conducted
	within last three years along with fee of	f Rs. 7,500/- for correction/pre-approval change in product /-11/2012-B&A/DRAP dated 07-05-2021, before issuance of
	registration letter.	
334.	Name and address of manufacturer/	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga
	Applicant	Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586)
		Eye Drops (general) Section
	Brand Name + Dosage Form +	Alrex-T Ophthalmic Suspension
	Strength	Timen T opiniumine Suspension
	Composition	Each 1ml contains;
		Loteprednol Etabonate5mg
		Tobramycin3mg
	Diary No. Date of R & I & fee	Dy. No. 14060 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0549396 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Antibiotics
	Tharmacological Group	ATC Code: S01AA12
		ANTIINFLAMMATORY AGENTS
		ATC Code: S01BA14
	Type of Form	Form-5
	Finished product Specification	USP Specifications. (not in pharmacopoeia)
	Pack size & Demanded Price	5mL. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Zylet 0.5%/0.3% ophthalmic Suspension USFDA Approved.
	Me-too status	Lotepred-T Ophtalmic Suspension Reg. No. 070515
	Ne too status	M/s Sante (Pvt.) ltd. Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
		• Specifications of finished product are mentioned as
		USP specs. Monograph for reference is required.
		s specifications. Firm shall submit latest GMP inspection
	1 -	long with fee of Rs. 7,500/- for correction/pre-approval change ation No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before
	issuance of registration letter.	
335.	Name and address of manufacturer/	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga
	Applicant	Raiwind Road, Manga Mandi, Distt Lahore. (DML No.
		000586)
	Brand Name + Dosage Form + Strength	Eye Drops (general) Section Careprost Ophthalmic Solution
	Composition	Each 1ml contains;
	Composition	Bimatoprost0.3mg
	Diary No. Date of R & I & fee	Dy. No. 14055 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0549393 dated 05-03-2019, endorsed on
		06.03.2019.
	Pharmacological Group	Prostaglandin analogues
		ATC Code: S01EE03
1	Type of Form	Form-5

	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	3ml. As per SRO.
	Approval status of product in Reference	BIMATOPROST NEON HEALTHCARE 0.3 MG/ML
	Regulatory Authorities	EYE DROPS, SOLUTION - PL 45043/0010
		MHRA Approved.
	Me-too status	Lureye Ophtalmic Solution 0.03% Reg. No. 083011
	CL (D	M/s Atco laboratories Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	conducted within last three years along v product specifications as per notification N of registration letter.	pecifications. Firm shall submit latest GMP inspection report with fee of Rs. 7,500/- for correction/pre-approval change in No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance
336.	Name and address of manufacturer/	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga
	Applicant	Raiwind Road, Manga Mandi, Distt Lahore. (DML No.
		000586)
		Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	Nevan Ophtalmic Suspension
	Composition	Each ml contains;
	Diam No Data of D % I % for	Nepafenac1mg
	Diary No. Date of R & I & fee	Dy. No. 14047 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0605444 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Antiinflammatory agents, non-steroids
	Tharmacological Gloup	ATC Code: S01BC10
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	5ml, As per SRO.
	Approval status of product in Reference	NEVANAC 1 MG/ML EYE DROPS SUSPENSION
		MIID A Ammayord
	Regulatory Authorities	MHRA Approved.
	Regulatory Authorities Me-too status	Nepatek Suspension Reg. No. 075286
	Me-too status	Nepatek Suspension Reg. No. 075286 M/s Innvotek Pharmaceuticals Islamabad.
	Me-too status GMP status	Nepatek Suspension Reg. No. 075286 M/s Innvotek Pharmaceuticals Islamabad. Report of 2018 is submitted.
	Me-too status	Nepatek Suspension Reg. No. 075286 M/s Innvotek Pharmaceuticals Islamabad.
	Me-too status GMP status Remarks of the Evaluator Decision: Approved with innovator's sylonducted within last three years along was product specifications as per notification of registration letter.	Nepatek Suspension Reg. No. 075286 M/s Innvotek Pharmaceuticals Islamabad. Report of 2018 is submitted. Latest GMP inspection report/ certificate is required. Decifications. Firm shall submit latest GMP inspection report with fee of Rs. 7,500/- for correction/pre-approval change in No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance
337.	Me-too status GMP status Remarks of the Evaluator Decision: Approved with innovator's syconducted within last three years along yproduct specifications as per notification Merchanism.	Nepatek Suspension Reg. No. 075286 M/s Innvotek Pharmaceuticals Islamabad. Report of 2018 is submitted. Latest GMP inspection report/certificate is required. Decifications. Firm shall submit latest GMP inspection report with fee of Rs. 7,500/- for correction/pre-approval change in No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586)
337.	Me-too status GMP status Remarks of the Evaluator Decision: Approved with innovator's syconducted within last three years along yproduct specifications as per notification of registration letter. Name and address of manufacturer/Applicant	Nepatek Suspension Reg. No. 075286 M/s Innvotek Pharmaceuticals Islamabad. Report of 2018 is submitted. Latest GMP inspection report/certificate is required. cecifications. Firm shall submit latest GMP inspection report with fee of Rs. 7,500/- for correction/pre-approval change in No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section
337.	Me-too status GMP status Remarks of the Evaluator Decision: Approved with innovator's sy conducted within last three years along y product specifications as per notification of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	Nepatek Suspension Reg. No. 075286 M/s Innvotek Pharmaceuticals Islamabad. Report of 2018 is submitted. • Latest GMP inspection report/ certificate is required. Decifications. Firm shall submit latest GMP inspection report with fee of Rs. 7,500/- for correction/pre-approval change in No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section Optidex-T Ophthalmic Suspension
337.	Me-too status GMP status Remarks of the Evaluator Decision: Approved with innovator's syconducted within last three years along yproduct specifications as per notification of registration letter. Name and address of manufacturer/Applicant	Nepatek Suspension Reg. No. 075286 M/s Innvotek Pharmaceuticals Islamabad. Report of 2018 is submitted. Latest GMP inspection report/ certificate is required. cecifications. Firm shall submit latest GMP inspection report with fee of Rs. 7,500/- for correction/pre-approval change in No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section Optidex-T Ophthalmic Suspension Each 1ml contains;
337.	Me-too status GMP status Remarks of the Evaluator Decision: Approved with innovator's sy conducted within last three years along y product specifications as per notification of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	Nepatek Suspension Reg. No. 075286 M/s Innvotek Pharmaceuticals Islamabad. Report of 2018 is submitted. • Latest GMP inspection report/ certificate is required. • Latest GMP inspection report with fee of Rs. 7,500/- for correction/pre-approval change in No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section Optidex-T Ophthalmic Suspension Each 1ml contains; Dexamethasone1mg
337.	Me-too status GMP status Remarks of the Evaluator Decision: Approved with innovator's sy conducted within last three years along y product specifications as per notification of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	Nepatek Suspension Reg. No. 075286 M/s Innvotek Pharmaceuticals Islamabad. Report of 2018 is submitted. Latest GMP inspection report/ certificate is required. Decifications. Firm shall submit latest GMP inspection report with fee of Rs. 7,500/- for correction/pre-approval change in No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section Optidex-T Ophthalmic Suspension Each 1ml contains; Dexamethasone1mg Tobramycin3mg Dy. No. 14052 dated 07.03.2019. Fee paid Rs. 20,000/-
337.	Me-too status GMP status Remarks of the Evaluator Decision: Approved with innovator's syconducted within last three years along yproduct specifications as per notification of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition	Nepatek Suspension Reg. No. 075286 M/s Innvotek Pharmaceuticals Islamabad. Report of 2018 is submitted. • Latest GMP inspection report/ certificate is required. Decifications. Firm shall submit latest GMP inspection report with fee of Rs. 7,500/- for correction/pre-approval change in No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section Optidex-T Ophthalmic Suspension Each 1ml contains; Dexamethasone1mg Tobramycin3mg
337.	Me-too status GMP status Remarks of the Evaluator Decision: Approved with innovator's syconducted within last three years along yproduct specifications as per notification of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition	Nepatek Suspension Reg. No. 075286 M/s Innvotek Pharmaceuticals Islamabad. Report of 2018 is submitted. Latest GMP inspection report/ certificate is required. Decifications. Firm shall submit latest GMP inspection report with fee of Rs. 7,500/- for correction/pre-approval change in No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586) Eye Drops (general) Section Optidex-T Ophthalmic Suspension Each 1ml contains; Dexamethasone1mg Tobramycin3mg Dy. No. 14052 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0605448 dated 05-03-2019, endorsed on

	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5ml. As per SRO.
	Approval status of product in Reference	TOBRAMYCIN + DEXAMETHASONE (3 MG/ML + 1
	Regulatory Authorities	MG/ML) EYE DROPS, SUSPENSION - PL 31103/0010
		MHRA Approved.
	Me-too status	Tobradex Suspension Reg. No. 017040
		M/s Novartis Pharma Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		r shall be issued after submission of valid GMP
	certificate or latest GMP inspection re	
338.	Name and address of manufacturer/	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga
	Applicant	Raiwind Road, Manga Mandi, Distt Lahore. (DML No.
		000586)
		Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	Fluoro-T ophthalmic suspension
	Composition	Each 1ml contains;
		Fluorometholone1mg
		Tetrahydrozoline HCl0.25mg
	Diary No. Date of R & I & fee	Dy. No. 14054 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0549392 dated 05-03-2019, endorsed on
		06.03.2019.
	Pharmacological Group	Sympathomimetics used as decongestants
		ATC Code: S01GA52
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	5ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified
	Me-too status	Femicon Ophthalmic suspension 5ml Reg. No. 012112
		M/s Remington Pharmaceutical Industries Lahore.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		• Evidence of approval of applied formulation in
		reference regulatory authorities/agencies which were
		adopted by the Registration Board in its 275 th meeting
		is required.
	Decision: Deferred for following:	
	 Evidence of approval of applied formu declared/approved by the Registration 	lation in reference regulatory authorities/agencies which were Board.
	• submission of valid GMP certificate	
339.	Name and address of manufacturer/	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga
	Applicant	Raiwind Road, Manga Mandi, Distt Lahore. (DML No.
		000586)
		Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	BIOPAT DS Ophthalmic solution (5ml)
	Composition	Each ml contains
		Olopatadine HCl 2.22mg eq. to Olopatadine2mg
	Diary No. Date of R & I & fee	Dy. No. 14056 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0605447 dated 05-03-2019, endorsed on

		06.03.2019.
	Pharmacological Group	Other antiallergics
	Thurmacorogreat Group	ATC Code: S01GX09
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5ml. As per SRO.
	Approval status of product in Reference	Olopatadine hydrochloride eq 0.2% base Solution
	Regulatory Authorities	Ophthalmic
	Regulatory Authorities	USFDA Approved.
	Me-too status	Optidine eye drops 0.2% Reg. No. 092845
	Me-too status	M/s Hudson Pharma Karachi.
	CMD status	
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		r shall be issued after submission of valid GMP
240	certificate or latest GMP inspection re	
340.	Name and address of manufacturer/	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga
	Applicant	Raiwind Road, Manga Mandi, Distt Lahore. (DML No.
		000586)
		Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	Biopat Ophthalmic solution
	Composition	Each ml contains
		Olopatadine HCl 1.11mg eq. to Olopatadine1mg
	Diary No. Date of R & I & fee	Dy. No. 14049 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0605446 dated 05-03-2019, endorsed on
		06.03.2019.
	Pharmacological Group	Other antiallergics ATC Code: S01GX09
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5ml. As per SRO.
	Approval status of product in Reference	Olopatadine 1mg/ml eye drops, solution - (olopatadine
	Regulatory Authorities	hydrochloride) - PL 04569/1366; UK/H/4541/001/DC
	regulatory regulatorities	MHRA Approved.
	Me-too status	Winolap 0.1% Ophthalmic solution Reg. No. 067397
	1.10 too status	M/s ATCO Laboratories Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Remarks of the Evaluator	Latest GWI Inspection report/ certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate or latest GMP inspection report.	
341.	Name and address of manufacturer/	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga
	Applicant	Raiwind Road, Manga Mandi, Distt Lahore. (DML No.
		000586)
		Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	Systears Lubricant eye drops
	Composition	Each ml contains;
	Composition	Polyethylene glycol4mg
		Propylene glycol3mg
	Diary No. Data of D. Pr. I. Pr. for	
	Diary No. Date of R & I & fee	Dy. No. 14048 dated 07.03.2019. Fee paid Rs. 20,000/-
		vide Slip No. 0605445 dated 05-03-2019, endorsed on
		06.03.2019.

	Pharmacological Group	Eye lubricant.
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications (not in pharmacopoeia)
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too status	EyeLub Reg. No. 063198 M/s Shaigan Rawalpindi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275 th meeting is required.
	Decision: Deferred for following:	•
	declared/approved by the Registration	
242	• submission of valid GMP certificate	
342.	Name and address of manufacturer/ Applicant	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586)
	Daniel Manage Daniel Campath	Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	UNILAT Ophthalmic Solution
	Composition	Each ml contains; Latanoprost50mcg
	Diary No. Date of R & I & fee	Dy. No. 14058 dated 07.03.2019. Fee paid Rs. 20,000/vide Slip No. 0549397 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Prostaglandin analogues ATC Code: S01EE01
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications (not in pharmacopoeia)
	Pack size & Demanded Price	2.5ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	LATOP 50 MICROGRAMS/ML EYE DROPS SOLUTION MHP A Approved
	Me-too status	MHRA Approved. Prostile eye Drops Reg. no. 029948
	Me-too status	M/s Remington Pharma Lahore.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	conducted within last three years along v	pecifications. Firm shall submit latest GMP inspection report with fee of Rs. 7,500/- for correction/pre-approval change in Io.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance
343.	Name and address of manufacturer/	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga
	Applicant	Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586)
	D 111 D 2	Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	CO-LATAN Ophthalmic Solution
	Composition	Each ml contains;
		Latanoprost50mcg

		Timolol maleate 6.85mg eq to timolol5mg
	Diary No. Date of R & I & fee	Dy. No. 14059 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0710229 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Ophthalmological-betablocking agents - timolol, combinations ATC code: S01ED51
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications (not in pharmacopoeia)
	Pack size & Demanded Price	2.5ml. As per SRO.
	Approval status of product in Reference	Latanoprost+Timolol 50 micrograms/ml 5 mg/ml eye
	Regulatory Authorities	drops solution - PL 18956/0020
		MHRA Approved.
	Me-too status	Xalacom Eye Drops Reg. No. 031386 M/s Pfizer Pakistan Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	conducted within last three years along v	pecifications. Firm shall submit latest GMP inspection report with fee of Rs. 7,500/- for correction/pre-approval change in No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance
344.	Name and address of manufacturer/	M/s. Searle IV Solutions (Pvt.) Ltd. 1.5KM, Manga
	Applicant	Raiwind Road, Manga Mandi, Distt Lahore. (DML No. 000586)
		Eye Drops (general) Section
	Brand Name + Dosage Form + Strength	Levoxin Ophthalmic Solution
	Composition	Each ml contains; Levofloxacin hemihydrate eq to levofloxacin15mg
	Diary No. Date of R & I & fee	Dy. No. 14053 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0555543 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Fluoroquinolones ATC Code: S01AE05
	Type of Form	Form-5
	Finished product Specification	USP Specifications (couldn't be found in USP, available in JP)
	Pack size & Demanded Price	5ml As non CDO
l		5ml. As per SRO.
	Approval status of product in Reference	LEVOFLOXACIN 5MG/ML EYE DROPS SOLUTION
	Approval status of product in Reference Regulatory Authorities	LEVOFLOXACIN 5MG/ML EYE DROPS SOLUTION MHRA Approved.
	Approval status of product in Reference	LEVOFLOXACIN 5MG/ML EYE DROPS SOLUTION
	Approval status of product in Reference Regulatory Authorities Me-too status GMP status	LEVOFLOXACIN 5MG/ML EYE DROPS SOLUTION MHRA Approved. Qumic eye drops Reg. No. 042185
	Approval status of product in Reference Regulatory Authorities Me-too status	LEVOFLOXACIN 5MG/ML EYE DROPS SOLUTION MHRA Approved. Qumic eye drops Reg. No. 042185 M/s Bosch Pharma Karachi.
	Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with JP specificati conducted within last three years along wi	LEVOFLOXACIN 5MG/ML EYE DROPS SOLUTION MHRA Approved. Qumic eye drops Reg. No. 042185 M/s Bosch Pharma Karachi. Report of 2018 is submitted.
345.	Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with JP specificatic conducted within last three years along with product specifications as per notification.	LEVOFLOXACIN 5MG/ML EYE DROPS SOLUTION MHRA Approved. Qumic eye drops Reg. No. 042185 M/s Bosch Pharma Karachi. Report of 2018 is submitted. Latest GMP inspection report/ certificate is required. ons. Firm shall submit latest GMP inspection report th fee of Rs. 7,500/- for correction/pre-approval change in

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Injectable Vial Cephalosporin Section. Brand Name + Dosage Form + Strength CEFOP Injection 2gm Composition Each vial contains;	
Composition Laci via contains,	
Cefoperazone Sodium equivalent to Cefoperz	rone 1o
Sulbactam Sodium equivalent to Sulbactam	_
Diary No. Date of R & I & fee Dy. No. 16820 dated 07.03.2019. Fee paid	
vide Slip No. 0817482 dated 07-03-2019,	
07.03.2019.	chaorsea on
Pharmacological Group J01DD62 cefoperazone and beta-lactama	ase inhibitor
Type of Form Form-5	ase minorior
Finished product Specification Not mentioned (Available in JP)	
Pack size & Demanded Price As per SRO.	
Approval status of product in Reference Approved in 03 European countries, i.e., Czec	ch
Regulatory Authorities Republic, Poland and Slovakia	
Me-too status Q-Bact 2gm Injection Reg. No. 061170	
M/s High-Q International Karachi.	
GMP status Certificate of 2018 is submitted.	
	ia na assina d
	-
Reference of finished product specification	
Decision: Approved with JP specifications. Registration letter shall be issued after	
of valid GMP certificate or latest GMP inspection report of M/s bloom, fee of Rs. 7	· -
SRO 496(I)/2023 dated 17.04.2023 and report of satisfactory capacity assessment o	
manufacturing & testing facility of M/s Bloom Pharmaceuticals (Pvt.) Ltd., Plot No.	o. 30, Phase-
I & II Industrial Estate, Hattar.	g
Name and address of manufacturer/ M/s. Webros Pharmaceuticls, Plot No. 1	
Applicant National Industrial Zone, Rawat (contract a	giver) (DML
No.000538)	
Contract with	DI 4 NI 20
M/s. Bloom Pharmaceuticals (Pvt.) Ltd., I	· ·
Phase-I & II Industrial Estate, Hattar (Contra	act Acceptor)
(DML No.000374) Injectable Vial Cephalosporin Section.	
Brand Name + Dosage Form + Strength CEFOP Injection 1gm	
Composition Each vial contains; Cefoperazone Sodium equivalent to	
Cefoperazone500mg	
Sulbactam Sodium equivalent to Sulbactam	500ma
Diary No. Date of R & I & fee Dy. No. 16821 dated 07.03.2019. Fee paid	
vide Slip No. 0817481 dated 07-03-2019,	
07.03.2019.	chaorsea on
Pharmacological Group J01DD62 cefoperazone and beta-lactama	osa inhihitar
Type of Form Form-5	isc illifottor
Finished product Specification Not mentioned (Available in JP)	
Pack size & Demanded Price As per SRO.	
	ECTION 1C
	DECTION IG
Me-too status Q-Bact 1gm Injection Reg. No. 061169	
M/s High-Q International Karachi.	
GMP status Certificate of 2018 is submitted.	
Remarks of the Evaluator • Latest GMP inspection report/ certificate in the control of the cont	-
Reference of finished product specification	ns is reuired.

	of valid GMP certificate or latest GMF SRO 496(I)/2023 dated 17.04.2023 and manufacturing & testing facility of M/I & II Industrial Estate, Hattar.	ions. Registration letter shall be issued after submission inspection report of M/s bloom, fee of Rs. 7,500/- as per report of satisfactory capacity assessment of Bloom Pharmaceuticals (Pvt.) Ltd., Plot No. 30, Phase-
349.	Name and address of manufacturer/ Applicant	M/s. Webros Pharmaceuticls, Plot No. 1, Street 10, National Industrial Zone, Rawat (contract giver) (DML No.000538)
		Contract with M/s. Bloom Pharmaceuticals (Pvt.) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar (Contract Acceptor) (DML No.000374) Injectable Vial Cephalosporin Section.
	Brand Name + Dosage Form + Strength	COV Injection 500mg
	Composition	Each vial contains;
	Composition	Cefepime as HCL with L-arginine eq to Cefepime500mg
	Diary No. Date of R & I & fee	Dy. No. 16823 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0817479 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01DE01 Fourth-generation cephalosporins
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Cefepime hydrochloride eq to 500mg base/ vial.
	Regulatory Authorities	USFDA Approved.
	Me-too status	Avepime Injection 500mg Reg. No. 059586 M/s Aventek Pharmaceuticals Lahore.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Decision: Approved with JP specifications. Registration letter shall be issued after submission of valid GMP certificate or latest GMP inspection report of M/s bloom and report of satisfactory capacity assessment of manufacturing & testing facility of M/s Bloom Pharmaceuticals (Pvt.) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar	
350.	Name and address of manufacturer/ Applicant	M/s. Webros Pharmaceuticls, Plot No. 1, Street 10, National Industrial Zone, Rawat (contract giver) (DML No.000538) Contract with
		M/s. Bloom Pharmaceuticals (Pvt.) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar (Contract Acceptor) (DML No.000374) Injectable Vial Cephalosporin Section.
	Brand Name + Dosage Form + Strength	COV Injection 1gm
	Composition	Each vial contains; Cefepime as HCL with L-arginine eq to Cefepime1g
	Diary No. Date of R & I & fee	Dy. No. 16822 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0817480 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01DE01 Fourth-generation cephalosporins
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	i misiica product specification	OSI Specifications

	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Cefepime hydrochloride eq to 1000mg base/ vial.
	Regulatory Authorities	USFDA Approved.
	Me-too status	Avepime Injection 1gm Reg. No. 059585
		M/s Aventek Pharmaceuticals Lahore.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	of valid GMP certificate or latest GMP SRO 496(I)/2023 dated 17.04.2023	ions. Registration letter shall be issued after submission inspection report of M/s Bloom, fee of Rs. 7,500/- as per and report of satisfactory capacity assessment of Bloom Pharmaceuticals (Pvt.) Ltd., Plot No. 30, Phase-
351.	Name and address of manufacturer/	M/s. Care Pharmaceuticals 8KM Thokar Raiwind Raod,
	Applicant	Lahore (DML No. 000563).
		Section
	Brand Name + Dosage Form + Strength	PAINCARE 5% W/W gel
	Composition	Each 100gram contains;
	_	Ibuprofen BP5%W/W
	Diary No. Date of R & I & fee	Dy. No. 16434 dated 07.03.2019. Fee paid Rs. 20,000/vide Slip No. 0812231 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Propionic acid derivatives ATC Code: M01AE01
	Type of Form	Form-5
	Finished product Specification	Not Mentioned
	Pack size & Demanded Price	25gm, 30gm. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only - PL 00063/0706-0707 MHRA Approved.
	Me-too status	Could not be verified.
	GMP status	Not submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Remarks of the Evaluator	 Section approval is required.
		1 1
	!	Reference of finished product specifications is required. Evidence of applied formulation (drug already approved).
	!	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith
		registration number, brand name and name of firm is
		required.
	Decision: Deferred for following;	required.
	Latest GMP inspection report/of	cartificata
	 Evidence of section approval. 	
		orm-5D along with stability study data as per the
	guidelines approved in 293 rd me	
352.	Name and address of manufacturer/	M/s. Care Pharmaceuticals 8KM Thokar Raiwind Road,
	Applicant Applicant	Lahore (DML No. 000563). Section
	Brand Name + Dosage Form + Strength	NEPCARE 0.1% Ophthalmic Suspension
		Fach ml of suspension contains:
	Composition	Each ml of suspension contains;

		Nepafenac1mg
	Diary No. Date of R & I & fee	Dy. No. 16433 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0812229 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Antiinflammatory agents, non-steroids ATC Code: S01BC10
	Type of Form	Form-5
	Finished product Specification	Not Mentioned
	Pack size & Demanded Price	5ml. As per SRO.
	Approval status of product in Reference	NEVANAC 1 MG/ML EYE DROPS SUSPENSION
	Regulatory Authorities	MHRA Approved.
	Me-too status	Nepanac Ophthalmic Suspension Reg. No. 069177 M/s Remington Pharma Lahore.
	GMP status	Not submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		Reference of finished product specifications is required.
	Decision: Approved with innovator's su	pecifications. Firm shall submit latest GMP inspection report
	conducted within last three years along v	with fee of Rs. 7,500/- for correction/pre-approval change in No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance
353.	Name and address of manufacturer/	M/s. Care Pharmaceuticals 8KM Thokar Raiwind Road,
	Applicant	Lahore (DML No. 000563).
		Section
	Brand Name + Dosage Form + Strength	GRAVICARE 12.5mg/5ml Syrup
	Composition	Each 5ml contains;
		Dimenhydrinate USP12.5mg
	Diary No. Date of R & I & fee	Dy. No. 16430 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0812232 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Aminoalkyl ethers
		ATC Code: R06AA11
	Type of Form	Form-5
	Finished product Specification	Not Mentioned
	Pack size & Demanded Price	60ml, 90ml, 120ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed for per 5ml
	GMP status	Not submitted.
	Remarks of the Evaluator	 Latest GMP inspection report/ certificate is required. Reference of finished product specifications is required. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status)
	Design Deformed for following	alongwith registration number, brand name and name of firm is required. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board is required.
	Decision: Deferred for following:	

	registration number, brand name and	lation in reference regulatory authorities/agencies which were Board.
354.	Name and address of manufacturer/ Applicant	M/s. Care Pharmaceuticals 8KM Thokar Raiwind Road, Lahore (DML No. 000563). Section
	Brand Name + Dosage Form + Strength	CAREPROFEN GEL 2.5% Gel
	Composition	Each gram contains; Ketoprofen BP25mg
	Diary No. Date of R & I & fee	Dy. No. 16429 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0812233 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Antiinflammatory preparations, non-steroids for topical use ATC Code: M02AA10
	Type of Form	Form-5
	Finished product Specification	Not Mentioned
	Pack size & Demanded Price	25gm, 30gm. As per SRO.
	Approval status of product in Reference	KETOPROFEN 2.5% W/W GEL
	Regulatory Authorities	MHRA Apprved.
	Me-too status	Fastum Topical Gel 2.5% Reg. No. 099502 M/s Pharmatec Pakistan Karachi.
	GMP status	Not submitted.
	Remarks of the Evaluator	 Latest GMP inspection report/ certificate is required. Reference of finished product specifications is
	required. Decision: Approved with innovator's specifications. Firm shall submit latest GMP inspection report conducted within last three years along with fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance	
	of registration letter.	doi:// 11/2012 Decla/Divil duted 0/ 05 2021, before issuance
355.	Name and address of manufacturer/ Applicant	M/s. Care Pharmaceuticals 8KM Thokar Raiwind Road, Lahore (DML No. 000563).
	D IN D E G	Section C. P. C. S. C. L.
	Brand Name + Dosage Form + Strength	PIROCARE 0.5% Gel
	Composition	Each gram contains;
	Diary No. Date of R & I & fee	Piroxicam5mg Dy. No. 16431 dated 07.03.2019. Fee paid Rs. 20,000/vide Slip No. 0812234 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Antiinflammatory preparations, non-steroids for topical use ATC Code: M02AA07
	Type of Form	Form-5
	Finished product Specification	Not Mentioned
	Pack size & Demanded Price	25gm. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Piroxicam Manx 0.5% w/w gel - PL 14251/0028 MHRA Approved.
	Me-too status	Feldene Gel 0.5% Reg. No. 012817 M/s Pfizer Pakistan Karachi

	GMP status	Not submitted.	
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is	
		required.	
		• Reference of finished product specifications is	
		required.	
	Decision: Approved with innovator's specifications.		
	Firm shall submit latest GMP inspection r	report conducted within last three years along with fee of Rs. e in product specifications as per notification No.F.7-11/2012-	
356.	Name and address of manufacturer/	M/s. Care Pharmaceuticals 8KM Thokar Raiwind Road,	
	Applicant	Lahore (DML No. 000563).	
		Section	
	Brand Name + Dosage Form + Strength	ALBENDACARE 200mg/5ml Suspension	
	Composition	Each 5ml contains;	
	1	Albendazole USP200mg	
	Diary No. Date of R & I & fee	Dy. No. 16432 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0812231 dated 05-03-2019, endorsed on 06.03.2019.	
	Pharmacological Group	Benzimidazole derivatives ATC Code: P02CA03	
	Type of Form	Form-5	
	Finished product Specification	Not Mentioned	
	Pack size & Demanded Price	10ml. As per SRO.	
	Approval status of product in Reference	Could not be verified.	
	Regulatory Authorities		
	Me-too status	Benza 200 suspension 200mg/5ml Reg. No. 059857 M/s Searle Company Lahore.	
	GMP status	Not submitted.	
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is	
	remains of the 2 valuation	required.	
		Reference of finished product specifications is	
		required.	
	Decision: Deferred for following: • Evidence of approval of applied f	ormulation in reference regulatory authorities/agencies	
	 which were declared/approved by t Latest GMP inspection report/ cert 	the Registration Board.	
357.	Name and address of manufacturer/	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial	
	Applicant	Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver).	
		Contract with	
		M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151	
		Sector 24, Korangi Industrial Area, Karachi. (DML	
		No.000167) contract acceptor	
	David Maria I David Ermin	Dry Powder Injection (Cephalosporin) Injection Section.	
	Brand Name + Dosage Form + Strength	Ceftranor 500mg IV Injection	
	Composition	Each vial contains;	
		Ceftriaxone sodium eq. to Ceftriaxone (USP)500mg	
	Diary No. Date of R & I & fee	Dy. No. 16047 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 08118830 dated 06-03-2019, endorsed on 07.03.2019.	
	Pharmacological Group	Third-generation cephalosporins.	
	1 Harring of ogical Of oup	Time Scholation copilatosporms.	

		ATC Code: J01DD04
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for
	Regulatory Authorities	Injection and 2g Pwder for Solution for Injection or
		Infusion - PL 22805/0001, 3-5
		MHRA Approved.
	Me-too status	Zetox 500mg Injection Reg. No. 053145
		M/s Lahore Pharma.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	
	letter upon consideration of satisfactory M/s Mediate Pharmaceutical (Pvt.) Ltd.	further authorized its Chairman for issuance of registration capacity assessment of manufacturing and testing facility of 150-151, Sector 24, Korangi Industrial Area, Karachi.
358.	Name and address of manufacturer/	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial
	Applicant	Triangle Kahuta Road, Islamabad (DML No. 000792)
		(contract giver).
		Contract with
		M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151
		Sector 24, Korangi Industrial Area, Karachi. (DML
		No.000167) contract acceptor
	D IV D E	Dry Powder Injection (Cephalosporin) Injection Section.
	Brand Name + Dosage Form + Strength	Ceftranor 1g IV Injection
	Composition	Each vial contains;
		Ceftriaxone sodium eq. to Ceftriaxone (USP)1g
	Diary No. Date of R & I & fee	Dy. No. 16048 dated 07.03.2019. Fee paid Rs. 50,000/-
		vide Slip No. 0811829 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for Injection and 2g Powder for Solution for Injection or Infusion - PL 22805/0001, 3-5 MHRA Approved.
	Me-too status	Rocephin IV/IM Injection 1gm Reg. No. 007014 M/s Martin Dow Karachi
	GMP status	Last inspection of M/s Mediate Pharma conducted on
	Remarks of the Evaluator	09.10.2020. GMP status is good.
		rd further authorized its Chairman for issuance of
	registration letter upon consideration	of satisfactory capacity assessment of manufacturing armaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi
359.	Name and address of manufacturer/	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial
	Applicant	Triangle Kahuta Road, Islamabad (DML No. 000792)
	Applicant	l ' '

		Contract with	
		M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151	
		Sector 24, Korangi Industrial Area, Karachi. (DML	
		No.000167) contract acceptor	
		Dry Powder Injection (Cephalosporin) Injection Section.	
	Brand Name + Dosage Form +	Ceftranor 2g IV Injection	
	Strength	, and the second	
	Composition	Each vial contains;	
	1	Ceftriaxone sodium eq. to Ceftriaxone (USP)2g	
	Diary No. Date of R & I & fee	Dy. No. 16054 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0844385 dated 06-03-2019, endorsed on 07.03.2019.	
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04	
	Type of Form	Form-5	
	Finished product Specification	USP Specifications.	
	Pack size & Demanded Price	As per SRO.	
	Approval status of product in Reference	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for	
	Regulatory Authorities	Injection and 2g Powder for Solution for Injection or	
	regulatory redifferences	Infusion - PL 22805/0001, 3-5	
		MHRA Approved.	
	Me-too status	Traxon 2gm IM/IV Injection Reg. No. 018248	
	THE too status	(Import)	
		M/s Akhai Agencies Karachi.	
	GMP status	Last inspection of M/s Mediate Pharma conducted on	
		09.10.2020. GMP status is good.	
	Remarks of the Evaluator		
	Decision: Approved. Registration Board further authorized its Chairman for issuance of		
	registration letter upon consideration of	of satisfactory consisty assessment of manufacturing	
	_	• • •	
	and testing facility of M/s Mediate Pha	rmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi	
	and testing facility of M/s Mediate Pha Industrial Area, Karachi.	rmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/	maceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi.	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792)	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/	mrmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver).	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver). Contract with	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section.	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. NORCEFF 1gm injection	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/ Applicant Brand Name + Dosage Form +	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. NORCEFF 1gm injection Each vial contains;	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. NORCEFF 1gm injection Each vial contains; Cefoperazone sodium500mg	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. NORCEFF 1gm injection Each vial contains;	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. NORCEFF 1gm injection Each vial contains; Cefoperazone sodium500mg	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. NORCEFF 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg Dy. No. 16052 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0844383 dated 06-03-2019, endorsed on 07.03.2019. Third-generation cephalosporins, cefoperazone and beta-lactamase inhibitor.	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. NORCEFF 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg Dy. No. 16052 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0844383 dated 06-03-2019, endorsed on 07.03.2019. Third-generation cephalosporins, cefoperazone and beta-	
360.	and testing facility of M/s Mediate Pha Industrial Area, Karachi. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee	mrmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. NORCEFF 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg Dy. No. 16052 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0844383 dated 06-03-2019, endorsed on 07.03.2019. Third-generation cephalosporins, cefoperazone and beta-lactamase inhibitor. ATC Code: J01DD62	

	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	SULPERAZONE FOR INTRAVENOUS INJECTION 1G
	Regulatory Authorities	PDMA JAPAN APPROVED.
	Me-too status	Q-Bact 1gm Injection Reg. No. 061169
		M/s High-Q International Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on
		09.10.2020. GMP status is good.
	Remarks of the Evaluator	i. The salt/hydrate of API is mentioned as is in label.
		Revision of label claim is required as per innovator
		product along with submission of full fee i.e. Rs.
		75000/-
		ii. Reference of product specifications is required.
	Decision: Approved with JP specification	ons and following label claim;
	Each vial contains;	
	Cefoperazone as sodium500mg	
	Sulbactam as sodium500mg	
		d its Chairman for issuance of registration letter upon
		assessment of manufacturing and testing facility of M/s
		0-151, Sector 24, Korangi Industrial Area, Karachi and rrection/pre-approval change in product label claim as per
		ated 07-05-2021, before issuance of registration letter.
361.	Name and address of manufacturer/	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial
0020	Applicant	Triangle Kahuta Road, Islamabad (DML No. 000792)
		(contract giver).
		Contract with
		M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151
		Sector 24, Korangi Industrial Area, Karachi. (DML
		No.000167) contract acceptor
		Dry Powder Injection (Cephalosporin) Injection Section.
	Brand Name + Dosage Form +	NORCEFF 1gm injection
	Strength	
	Composition	Each vial contains;
		Cefoperazone sodium1000mg
	Di N D CD 0 I 0 C	Sulbactam sodium1000mg
	Diary No. Date of R & I & fee	Dy. No. 16053 dated 07.03.2019. Fee paid Rs. 50,000/-
		vide Slip No. 0844384 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins, cefoperazone and beta-
	Filarmacological Group	lactamase inhibitor.
		ATC Code: J01DD62
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Approved in 03 European countries, i.e., Czech Republic,
	Regulatory Authorities	Poland and Slovakia
	Me-too status	Q-Bact 2gm Injection Reg. No. 061170
		M/s High-Q International Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	i. The salt/hydrate of API is mentioned as is in label. Revision of label claim is required as per innovator product along with submission of full fee i.e. Rs. 75000/-

		ii. Reference of product specifications is required.	
	Decision: Approved with JP specificat	ions and following label claim;	
	Each vial contains;		
	Cefoperazone as sodium1000mg		
	Sulbactam as sodium1000mg		
	Registration Board further authorize	d its Chairman for issuance of registration letter upon	
	consideration of satisfactory capacity	assessment of manufacturing and testing facility of M/s	
	Mediate Pharmaceutical (Pvt.) Ltd. 15	50-151, Sector 24, Korangi Industrial Area, Karachi and	
	· · · · · · · · · · · · · · · · · · ·	orrection/pre-approval change in product label claim as per	
		lated 07-05-2021, before issuance of registration letter.	
362.	Name and address of manufacturer/	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial	
	Applicant	Triangle Kahuta Road, Islamabad (DML No. 000792)	
		(contract giver).	
		Contract with	
		M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151	
		Sector 24, Korangi Industrial Area, Karachi. (DML	
		No.000167) contract acceptor	
		Capsule (Cephalosporin) Section.	
	Drand Name Dogge Form	NORXIME 400mg Capsule	
	Brand Name + Dosage Form + Strength	NORATIVIE 400ting Capsule	
	Composition	Each Capsule Contains;	
	Composition	Cefixime as Cefixime trihydrate400mg	
	Diary No. Date of R & I & fee		
	Diary No. Date of R & I & fee	Dy. No. 16050 dated 07.03.2019. Fee paid Rs. 50,000/-	
		vide Slip No. 0811826 dated 06-03-2019, endorsed on	
	N 1 : 1 C	07.03.2019.	
	Pharmacological Group	Third-generation cephalosporins	
		ATC Code: J01DD08	
	Type of Form	Form-5	
	Finished product Specification	Not mentioned	
	Pack size & Demanded Price	As per SRO.	
	Approval status of product in Reference	SUPRAX (CEFIXIME) CAPSULES 400MG	
	Regulatory Authorities	USFDA APPROVED.	
	Me-too status	Cefspan 400mg Capsules Reg. No. 013860	
		M/s Barret Hodgson Pakistan Karachi.	
	GMP status	Last inspection of M/s Mediate Pharma conducted on	
		09.10.2020. GMP status is good.	
	Remarks of the Evaluator	• Reference of finished product specifications is	
		required.	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of		
	registration letter upon consideration of satisfactory capacity assessment of manufacturing		
	_	armaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi	
	Industrial Area, Karachi.	irmaceuticai (1 vi.) Diu. 150-151, Sector 24, Korangi	
363.	Name and address of manufacturer/	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial	
363.	Applicant	Triangle Kahuta Road, Islamabad (DML No. 000792)	
	Applicant		
		(contract giver).	
		Contract with	
		M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151	
		Sector 24, Korangi Industrial Area, Karachi. (DML	
		No.000167) contract acceptor	
		Dry Suspension (Cephalosporin) Section.	
	Brand Name + Dosage Form +	NORXIME 100mg/5ml Suspension	
	Strength		

	Composition	Each 5ml Contains;
		Cefixime as Cefixime trihydrate100mg
	Diary No. Date of R & I & fee	Dy. No. 16051 dated 07.03.2019. Fee paid Rs. 50,000/-
		vide Slip No. 0811827 dated 06-03-2019, endorsed on
		07.03.2019.
	Pharmacological Group	Third-generation cephalosporins
		ATC Code: J01DD08
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Cefixime 100 mg/5 mL Powder for Oral Suspension - PL
	Regulatory Authorities	04569/1118; UK/H/2828/001/DC
		MHRA Approved.
	Me-too status	Fixicef Powder for oral suspension Reg. No. 080273
		M/s Atco Laboratories Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on
		09.10.2020. GMP status is good.
	Remarks of the Evaluator	Reference of finished product specifications is
		required.
	Decision: Approved. Registration Boar	d further authorized its Chairman for issuance of
		of satisfactory capacity assessment of manufacturing
		rmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi
	Industrial Area, Karachi.	
364.	Name and address of manufacturer/	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial
	Applicant	Triangle Kahuta Road, Islamabad (DML No. 000792)
		(contract giver).
		Contract with
		M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151
		Sector 24, Korangi Industrial Area, Karachi. (DML
		No.000167) contract acceptor
		Dry Suspension (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	NORXIME 200mg/5ml Suspension
	Composition	Each 5ml Contains;
		Cefixime as Cefixime trihydrate200mg
	Diary No. Date of R & I & fee	Dy. No. 16049 dated 07.03.2019. Fee paid Rs. 50,000/-
		vide Slip No. 0811825 dated 06-03-2019, endorsed on
		07.03.2019.
	Pharmacological Group	Third-generation cephalosporins
		ATC Code: J01DD08
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Suprax 200mg/5ml
	Regulatory Authorities	USFDA Approved.
	Me-too status	Cefspan D.S Suspension Reg. No. 024634
		M/s Barret Hodgson Pakistan Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on
		09.10.2020. GMP status is good.
	Remarks of the Evaluator	Reference of finished product specifications is
		required.
	Decision: Approved. Registration Boar	d further authorized its Chairman for issuance of
		of satisfactory capacity assessment of manufacturing

	and testing facility of M/s Mediate Pha Industrial Area, Karachi.	rmaceutical (Pvt.) Ltd. 150-151, Sector 24, Korangi	
365.	Name and address of manufacturer/	M/s. Zeta Pharmaceuticals 494, Sunder Industrial Estate,	
	Applicant	Raiwind Road, Lahore (DML No. 000818).	
		Capsule (general) Section	
	Brand Name + Dosage Form + Strength	GABIPRO 50mg Capsule	
	Composition	Each Capsule Contains;	
		Pregabalin50mg	
	Diary No. Date of R & I & fee	Dy. No. 16900 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0806292 dated 06-03-2019, endorsed on 07.03.2019.	
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16	
	Type of Form	Form-5	
	Finished product Specification	Not mentioned.	
	Pack size & Demanded Price	As per SRO.	
	Approval status of product in Reference	PREGABALIN MSN 50 MG HARD CAPSULES - PL	
	Regulatory Authorities	50805/0037	
		MHRA Approved.	
	Me-too status	Gabica 50mg Cap Reg. No. 048725	
		M/s Getz Pharma Karachi	
	GMP status	Certificate issued on basis of inspection of 2017 is submitted.	
	Remarks of the Evaluator	 Reference of finished product specifications is required. Latest GMP certificate/inspection report is required. 	
	Decision: Approved with BP Specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.		
366.	Name and address of manufacturer/	M/s. Zeta Pharmaceuticals 494, Sunder Industrial Estate,	
	Applicant	Raiwind Road, Lahore (DML No. 000818).	
		Tablet (general) Section	
	Brand Name + Dosage Form + Strength	Zesyl 2mg Tablet	
	Composition	Each Tablet Contains;	
		Perindopril (as terbutylamine)2mg	
	Diary No. Date of R & I & fee	Dy. No. 15997 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0806283 dated 06-03-2019, endorsed on 07.03.2019.	
	Pharmacological Group	ACE inhibitors, plain	
	Tharmacological Gloup	ATC Code: C09AA04	
	Type of Form	Form-5	
	Finished product Specification	Not mentioned.	
	Pack size & Demanded Price	10's. As per SRO.	
	Approval status of product in Reference	PERINDOPRIL ERBUMINE 2 MG FILM-COATED	
	Regulatory Authorities	TABLETS - PL 49565/0046 MHRA Approved.	
	Me-too status	Peripril 2mg Tablet Reg. No. 037057 M/s Macter International Karachi.	
	GMP status	Certificate issued on basis of inspection of 2017 is submitted.	

Applicant Raiwind Road, Lahore (DML No. 000818). Tablet (general) Section Brand Name + Dosage Form + Strength Zesyl 4mg Tablet Composition Each Tablet Contains; Perindopril (as terbutylamine)4mg Diary No. Date of R & I & fee Dy. No. 15998 dated 07.03.2019. Fee paid Rs. 20,00 vide Slip No. 0806284 dated 06-03-2019, endorsed 07.03.2019. Pharmacological Group ACE inhibitors, plain ATC Code: C09AA04 Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Reference Reference Regulatory Authorities Me-too status Peripril 4mg Tablet Reg. No. 037058 M/s Macter International Karachi.		Remarks of the Evaluator Decision: Approved with USP specifications	 Reference of finished product specifications is required. Latest GMP certificate/inspection report is required. Product approved in RRA is film coated. Applied product is uncoated. Correction along with fee of Rs. 7500/- is required.
Name and address of manufacturer/ Applicant		Perindopril (as terbutylamine)2mg Firm shall submit latest GMP inspection 17,500/- for correction/pre-approval change	report conducted within last three years along with fee of Rs. ge in product description as per notification No.F.7-11/2012-
Composition Each Tablet Contains; Perindopril (as terbutylamine)4mg Diary No. Date of R & I & fee Dy. No. 15998 dated 07.03.2019. Fee paid Rs. 20,00 vide Slip No. 0806284 dated 06-03-2019, endorsed 07.03.2019. Pharmacological Group ACE inhibitors, plain ATC Code: C09AA04 Type of Form Form-5 Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Metoo status Peripril 4mg Tablet Reg. No. 037058 M/s Macter International Karachi.	367.	Name and address of manufacturer/	M/s. Zeta Pharmaceuticals 494, Sunder Industrial Estate, Raiwind Road, Lahore (DML No. 000818).
Composition Each Tablet Contains; Perindopril (as terbutylamine)4mg Diary No. Date of R & I & fee Dy. No. 15998 dated 07.03.2019. Fee paid Rs. 20,00 vide Slip No. 0806284 dated 06-03-2019, endorsed 07.03.2019. Pharmacological Group ACE inhibitors, plain ATC Code: C09AA04 Type of Form Form-5 Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Metoo status Peripril 4mg Tablet Reg. No. 037058 M/s Macter International Karachi.		Brand Name + Dosage Form + Strength	Zesyl 4mg Tablet
vide Slip No. 0806284 dated 06-03-2019, endorsed 07.03.2019. Pharmacological Group ACE inhibitors, plain ATC Code: C09AA04 Type of Form Form-5 Finished product Specification Not mentioned. Pack size & Demanded Price 10's. As per SRO. Approval status of product in Reference Regulatory Authorities PERINDOPRIL ERBUMINE 4 MG FILM-COATI TABLETS - PL 21880/0216 Me-too status Peripril 4mg Tablet Reg. No. 037058 M/s Macter International Karachi.			Each Tablet Contains;
ATC Code: C09AA04 Type of Form Form-5 Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities TABLETS - PL 21880/0216 MHRA Approved. Me-too status Peripril 4mg Tablet Reg. No. 037058 M/s Macter International Karachi.		Diary No. Date of R & I & fee	Dy. No. 15998 dated 07.03.2019. Fee paid Rs. 20,000/-vide Slip No. 0806284 dated 06-03-2019, endorsed on 07.03.2019.
Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities TABLETS - PL 21880/0216 MHRA Approved. Me-too status Peripril 4mg Tablet Reg. No. 037058 M/s Macter International Karachi.		Pharmacological Group	
Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status PERINDOPRIL ERBUMINE 4 MG FILM-COATI TABLETS - PL 21880/0216 MHRA Approved. Peripril 4mg Tablet Reg. No. 037058 M/s Macter International Karachi.		Type of Form	Form-5
Approval status of product in Reference Regulatory Authorities TABLETS - PL 21880/0216 MHRA Approved. Me-too status Peripril 4mg Tablet Reg. No. 037058 M/s Macter International Karachi.		Finished product Specification	Not mentioned.
Regulatory Authorities TABLETS - PL 21880/0216 MHRA Approved. Me-too status Peripril 4mg Tablet Reg. No. 037058 M/s Macter International Karachi.			*
Me-too status Peripril 4mg Tablet Reg. No. 037058 M/s Macter International Karachi.			TABLETS - PL 21880/0216
		Me-too status	Peripril 4mg Tablet Reg. No. 037058
submitted.		GMP status	Certificate issued on basis of inspection of 2017 is
required. • Latest GMP certificate/inspection report required. • Product approved in RRA is film coated. Apply product is uncoated. Correction along with fee		Remarks of the Evaluator	required. • Latest GMP certificate/inspection report is required. • Product approved in RRA is film coated. Applied product is uncoated. Correction along with fee of
Rs. 7500/- is required. Decision: Approved with USP specifications with following label; Each Film Coated Tablet Contains; Perindopril (as terbutylamine)4mg Firm shall submit latest GMP inspection report conducted within last three years along with fee of R 7,500/- for correction/pre-approval change in product description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.		Each Film Coated Tablet Contains; Perindopril (as terbutylamine)4mg Firm shall submit latest GMP inspection r 7,500/- for correction/pre-approval change	report conducted within last three years along with fee of Rs. e in product description as per notification No.F.7-11/2012-
Name and address of manufacturer/ Applicant M/s. Zeta Pharmaceuticals 494, Sunder Industrial Esta Raiwind Road, Lahore (DML No. 000818).	368.	Name and address of manufacturer/	M/s. Zeta Pharmaceuticals 494, Sunder Industrial Estate, Raiwind Road, Lahore (DML No. 000818).
Tablet (general) Section			
Brand Name + Dosage Form + Strength Zesyl 8mg Tablet Composition Each Tablet Contains;			

		Perindopril (as terbutylamine)8mg	
	Diary No. Date of R & I & fee	Dy. No. 15999 dated 07.03.2019. Fee paid Rs. 20,000/-	
	Diary No. Date of R & I & Ice	vide Slip No. 0806285 dated 06-03-2019, endorsed on	
		07.03.2019.	
	Pharmacological Group	ACE inhibitors, plain	
	Thatmacological Group	ATC Code: C09AA04	
	Type of Form	Form-5	
	Finished product Specification	Not mentioned.	
	Pack size & Demanded Price	10's. As per SRO.	
	Approval status of product in Reference	PERINDOPRIL ERBUMINE 8 MG FILM-COATED	
	Regulatory Authorities	TABLETS - PL 21880/0217	
	Regulatory Fluthorities	MHRA Approved.	
	Me-too status	Hartace Tablets 8mg Reg. No. 064429	
	THE too status	M/s CSH Pharma Peshawar.	
	GMP status	Certificate issued on basis of inspection of 2017 is	
	GM status	submitted.	
	Remarks of the Evaluator	Reference of finished product specifications is	
	Remarks of the Evaluator	required.	
		• Latest GMP certificate/inspection report is	
		required.	
		 Product approved in RRA is film coated. Applied 	
		product is uncoated. Correction along with fee of	
		Rs. 7500/- is required.	
	Decision: Approved with USP specifica	.	
	Each Film Coated Tablet Contains;		
	Perindopril (as terbutylamine)8mg		
		report conducted within last three years along with fee of Rs.	
	I II III SHall Sashille latest Sivil Inspection	eport conducted within last times years along with rec of Ks.	
	7,500/- for correction/pre-approval change	ge in product description as per notification No.F.7-11/2012-	
2.00	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu	ge in product description as per notification No.F.7-11/2012- ance of registration letter.	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issue Name and address of manufacturer/	ge in product description as per notification No.F.7-11/2012- ance of registration letter. M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu	ge in product description as per notification No.F.7-11/2012- ance of registration letter. M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386)	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issue Name and address of manufacturer/	ge in product description as per notification No.F.7-11/2012- ance of registration letter. M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver).	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issue Name and address of manufacturer/	te in product description as per notification No.F.7-11/2012- ance of registration letter. M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issue Name and address of manufacturer/	me in product description as per notification No.F.7-11/2012- ance of registration letter. M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issue Name and address of manufacturer/	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issue Name and address of manufacturer/	me in product description as per notification No.F.7-11/2012-ance of registration letter. M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant	mys. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section.	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection Each vial contains;	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection Each vial contains; Cefoperazone sodium500mg	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg Dy. No. 16201 dated 07.03.2019. Fee paid Rs. 50,000/-	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg Dy. No. 16201 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0825761 dated 05-03-2019, endorsed on	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg Dy. No. 16201 dated 07.03.2019. Fee paid Rs. 50,000/vide Slip No. 0825761 dated 05-03-2019, endorsed on 06.03.2019.	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg Dy. No. 16201 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0825761 dated 05-03-2019, endorsed on 06.03.2019. Third-generation cephalosporins, cefoperazone and beta-	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg Dy. No. 16201 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0825761 dated 05-03-2019, endorsed on 06.03.2019. Third-generation cephalosporins, cefoperazone and beta-lactamase inhibitor.	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg Dy. No. 16201 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0825761 dated 05-03-2019, endorsed on 06.03.2019. Third-generation cephalosporins, cefoperazone and betalactamase inhibitor. ATC Code: J01DD62	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issue Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form	me in product description as per notification No.F.7-11/2012- ance of registration letter. M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg Dy. No. 16201 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0825761 dated 05-03-2019, endorsed on 06.03.2019. Third-generation cephalosporins, cefoperazone and betalactamase inhibitor. ATC Code: J01DD62 Form-5	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification	me in product description as per notification No.F.7-11/2012- ance of registration letter. M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg Dy. No. 16201 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0825761 dated 05-03-2019, endorsed on 06.03.2019. Third-generation cephalosporins, cefoperazone and betalactamase inhibitor. ATC Code: J01DD62 Form-5 Not mentioned	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	ge in product description as per notification No.F.7-11/2012- ance of registration letter. M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg Dy. No. 16201 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0825761 dated 05-03-2019, endorsed on 06.03.2019. Third-generation cephalosporins, cefoperazone and beta- lactamase inhibitor. ATC Code: J01DD62 Form-5 Not mentioned As per SRO.	
369.	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification	me in product description as per notification No.F.7-11/2012- ance of registration letter. M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section. RAKAZONE 1gm injection Each vial contains; Cefoperazone sodium500mg Sulbactam sodium500mg Dy. No. 16201 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0825761 dated 05-03-2019, endorsed on 06.03.2019. Third-generation cephalosporins, cefoperazone and betalactamase inhibitor. ATC Code: J01DD62 Form-5 Not mentioned	

	Me-too status	Q-Bact 1gm Injection Reg. No. 061169	
	THE too states	M/s High-Q International Karachi.	
	GMP status	Last inspection of M/s Mediate Pharma conducted on	
		09.10.2020. GMP status is good.	
	Remarks of the Evaluator	i. The salt/hydrate of API is mentioned as is in label. Revision of label claim is required as per innovator	
		product along with submission of full fee i.e. Rs.	
		75000/-	
	Designar Approved with ID specificati	ii. Reference of product specifications is required.	
	Decision: Approved with JP specificati Each vial contains;	ons and following label claim;	
	Cefoperazone as sodium500mg		
	Sulbactam as sodium500mg		
	Registration Board further authorized its Chairman for issuance of registration letter upon		
		assessment of manufacturing and testing facility of M/s	
		0-151, Sector 24, Korangi Industrial Area, Karachi and	
		rrection/pre-approval change in product label claim as per	
	notification No.F.7-11/2012-B&A/DRAP d		
370.	Name and address of manufacturer/	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial	
	Applicant	Estate, Hayatabad, Peshawar (DML No. 000386)	
		(contract giver).	
		Contract with	
		M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151	
		Sector 24, Korangi Industrial Area, Karachi. (DML	
		No.000167) contract acceptor	
	D IN D E G	Dry Powder Injection (Cephalosporin) Injection Section.	
	Brand Name + Dosage Form + Strength	RAKAZONE 2gm injection	
	Composition	Each vial contains;	
		Cefoperazone sodium1000mg Sulbactam sodium1000mg	
	Diary No. Date of R & I & fee	Dy. No. 16202 dated 07.03.2019. Fee paid Rs. 50,000/-	
	Diary No. Date of R & T & Ice	vide Slip No. 0825762 dated 05-03-2019, endorsed on	
		06.03.2019.	
	Pharmacological Group	Third-generation cephalosporins, cefoperazone and beta-	
		lactamase inhibitor.	
		ATC Code: J01DD62	
	Type of Form	Form-5	
	Finished product Specification	Not mentioned	
	Pack size & Demanded Price	As per SRO.	
	Approval status of product in Reference	Approved in 03 European countries, i.e., Czech Republic,	
	Regulatory Authorities	Poland and Slovakia	
	Me-too status	Q-Bact 2gm Injection Reg. No. 061170	
		M/s High-Q International Karachi.	
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.	
	Remarks of the Evaluator	i. The salt/hydrate of API is mentioned as is in label.	
	2	Revision of label claim is required as per innovator	
		product along with submission of full fee i.e. Rs.	
		75000/-	
		ii. Reference of product specifications is required.	
	Decision: Approved with JP specifications and following label claim;		
	Each vial contains;	,	
	Cefoperazone as sodium1000mg		

	Sulbactam as sodium1000mg	
	Registration Board further authorized consideration of satisfactory capacity Mediate Pharmaceutical (Pvt.) Ltd. 15	d its Chairman for issuance of registration letter upon assessment of manufacturing and testing facility of M/s 50-151, Sector 24, Korangi Industrial Area, Karachi and orrection/pre-approval change in product label claim as per
	notification No.F.7-11/2012-B&A/DRAP d	
371.	Name and address of manufacturer/ Applicant	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver).
		Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor
		Dry Powder (General) Injection Section.
	Brand Name + Dosage Form + Strength	LOZAMEP 40mg Infusion (IV)
	Composition	Each vial Contains;
		Omeprazole40mg
	Diary No. Date of R & I & fee	Dy.No. 16200 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0825760 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Proton pump inhibitors. ATC Code: A02BC01
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion (omeprazole sodium) - PL 10622/0232 MHRA APPROVED.
	Me-too status	Risek 40mg Infusion Reg. No. 024170 M/s Getz Pharma Karachi.
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	i. The salt/hydrate of API is not considered in label. Revision of label claim is required as per innovator product along with submission of full fee i.e. Rs. 75000/-
		ii. Reference of product specifications is required.
	Decision: Approved with innovator's s Each vial contains; Omeprazole Sodium equivalent to Om	pecifications and following label claim;
	Registration Board further authorized consideration of satisfactory capacity Mediate Pharmaceutical (Pvt.) Ltd. 15 submission of fee of Rs. 7,5000/- for corr per notification No.F.7-11/2012-B&A/DR	d its Chairman for issuance of registration letter upon assessment of manufacturing and testing facility of M/s 50-151, Sector 24, Korangi Industrial Area, Karachi and rection/pre-approval change in salt form of drug substance as AP dated 07-05-2021.
372.	Name and address of manufacturer/ Applicant	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar (DML No. 000386) (contract giver).
		Contract with M/s Nortech Pharmaceuticals (pvt.) Ltd. 203, Industrial Triangle Kahuta Road Islamabad. (DML No.000792) contract acceptor Liquid Ampoule (General) Section.

	Brand Name + Dosage Form + Strength	RAKA Injection 5mg/ml
	Composition	Each 1ml Ampoule contains;
	Composition	Colecalciferol5mg
		Colectate in Croit
	Diary No. Date of R & I & fee	Dy. No. 16209 dated 07.03.2019. Fee paid Rs. 50,000/-
		vide Slip No. 0825773 dated 06-03-2019, endorsed on
		06.03.2019.
	Pharmacological Group	Vitamin D
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	VITAMIN D3 BON 200,000 IU/1 ml solution for injection
	Regulatory Authorities	IM ampoule
		ANSM France Approved.
	Me-too status	Sunny D Insta Ampoule Reg. No. 063450
		M/s Scotmann Pharmaceuticals Islamabad.
	GMP status	Last inspection of M/s Mediate Pharma conducted on
		29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with innovator's s	pecifications.
	Registration Board further authorized	d its Chairman for issuance of registration letter upon
	consideration of satisfactory capacity	assessment of manufacturing and testing facility of M/s
	Nortech Pharmaceuticals (pvt.) Ltd.	203, Industrial Triangle Kahuta Road Islamabad and
		rection/pre-approval change in product specifications as per
		ated 07-05-2021, before issuance of registration letter.
373.	Name and address of manufacturer/	M/s. Universal Pharmaceuticals (pvt.) Ltd. 131-A,
	Applicant	Industrial Estate, Hayatabad, Peshawar. (DML No.
		000545)
	D IN D	Tablet (General) Section.
	Brand Name + Dosage Form + Strength	HEPDISOL 550mg Tablet
	Composition	Each tablet contains;
	Composition	Rifaximin550mg
	Diary No. Date of R & I & fee	Dy.No. 16438 dated 07-03-2019; Fee Rs.20,000 paid vide
	Dialy 110. But of R & I & Ice	slip No. 0805858 dated 06.03.2019, endorsed on
		07.03.2019
	Pharmacological Group	Antibiotics
	Timinuo orogicus oroup	ATC Code: A07AA11
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	TARGAXAN 550 MG FILM-COATED TABLETS
	Regulatory Authorities	MHRA AAPPROVED.
	Me-too status	Rifaxa 550mg Tablet Reg. No. 071661
		M/s Ferozsons Laboratories Nowshera
	GMP status	Report dated 09.01.2019 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report is required.
		Reference of finished product specifications is
		required.
		Innovator product is film coated, applied is
		uncoated. Correction along with fee of Rs. 7500/- is
		required.
		1240000

	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu	report conducted within last three years along with fee of Rs. ge in product description as per notification No.F.7-11/2012-ance of registration letter.
374.	Name and address of manufacturer/ Applicant	M/s. Universal Pharmaceuticals (pvt.) Ltd. 131-A, Industrial Estate, Hayatabad, Peshawar. (DML No. 000545) Tablet (General) Section.
	Brand Name + Dosage Form + Strength	HEPDISOL 200mg Tablet
	Composition	Each tablet contains; Rifaximin200mg
	Diary No. Date of R & I & fee	Dy.No. 16437 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0805857 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Antibiotics ATC Code: A07AA11
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	XIFAXANTA 200 MG FILM-COATED TABLETS MHRA AAPPROVED.
	Me-too status	Zerifex 200mg Tablet Reg. No. 070709 M/s AGP (Pvt.) Ltd. Karachi.
	GMP status	Report dated 09.01.2019 is submitted.
	Remarks of the Evaluator	 Latest GMP inspection report is required. Reference of finished product specifications is required. Innovator product is film coated, applied is uncoated. Correction along with fee of Rs. 7500/- is required.
	Decision: Approved with innovator's specifications and following label; Each film tablet contains; Rifaximin200mg Firm shall submit latest GMP inspection report conducted within last three years along with fee of Rs. 7,500/- for correction/pre-approval change in product description as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
375.	Name and address of manufacturer/ Applicant	M/s. Universal Pharmaceuticals (pvt.) Ltd. 131-A, Industrial Estate, Hayatabad, Peshawar. (DML No. 000545) Capsule (Ceph) Section.
	Brand Name + Dosage Form + Strength	CEPOSAL 100mg Capsule
	Composition	Each capsule contains; Cefpodoxime (as proxetil)100mg
	Diary No. Date of R & I & fee	Dy.No. 16434 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0805854 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD13
	Type of Form	Form-5

	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status	Medidoxim Capsule 100mg Reg. no. 062564 M/s Medisave Pharmaceuticals Lahore.
	GMP status	Report dated 09.01.2019 is submitted.
	Remarks of the Evaluator	 Latest GMP inspection report is required. Reference of finished product specifications is required.
		Evidence of product approval in RRA is required.
	which were declared/approved by tLatest GMP inspection report.	
376.	Reference of finished product speci Name and address of manufacturer/	
370.	Applicant	M/s. Universal Pharmaceuticals (pvt.) Ltd. 131-A, Industrial Estate, Hayatabad, Peshawar. (DML No. 000545) Capsule (Ceph) Section.
	Brand Name + Dosage Form + Strength	CEPOSAL 200mg Capsule
	Composition	Each capsule contains; Cefpodoxime (as proxetil)200mg
	Diary No. Date of R & I & fee	Dy.No. 16436 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0805856 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD13
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status	Could not be confirmed.
	GMP status	Report dated 09.01.2019 is submitted.
	Remarks of the Evaluator	 Latest GMP inspection report is required. Reference of finished product specifications is required. Evidence of me-too and product approval in RRA
		is required.
	Decision: Deferred for following:	•
	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
	• Evidence of approval of applied for which were declared/approved by t	ormulation in reference regulatory authorities/agencies the Registration Board.
	• Latest GMP inspection report.	
	Reference of finished product speci	
377.	Name and address of manufacturer/ Applicant	M/s. Universal Pharmaceuticals (pvt.) Ltd. 131-A, Industrial Estate, Hayatabad, Peshawar. (DML No. 000545) Dry Suspension (Ceph) Section.
		Dry Buspension (Cepil) Beenon.

	Brand Name + Dosage Form +	CEPOSAL 40mg/5ml Oral Suspension
	Strength	
	Composition	Each 5ml of reconstituted suspension contains; Cefpodoxime (as proxetil)40mg
	Diary No. Date of R & I & fee	Dy.No. 16435 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0805855 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD13
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	CEFPODOXIME PROXETIL 40MG/5ML POWDER
	Regulatory Authorities	FOR ORAL SUSPENSION MHRA APPROVED.
	Me-too status	Doxicef Dry Suspension Reg. No. 045801
		M/s Synchro Pharmaceuticals Lahore.
	GMP status	Report dated 09.01.2019 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report is required.
		Reference of finished product specifications is required.
		report conducted within last three years along with fee of Rs. e in product specifications as per notification No.F.7-11/2012-ance of registration letter.
378.	Name and address of manufacturer/	M/s. Perk Pharma(Pvt.) Ltd. Plot No. 197/1-B, Main Road,
	Applicant	Industrial Estate, Gadoon Pakistan (DML No. 000857) (contract giver).
		Contract with
		M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section.
	Brand Name + Dosage Form +	HICEF500mg IV Injection
	Strength	The Li Soonig IV injection
	Composition	Each vial contains;
	Composition	Ceftriaxone sodium eq. to Ceftriaxone (USP)500mg
	Diary No. Date of R & I & fee	Dy. No. 16949 dated 07.03.2019. Fee paid Rs. 50,000/-vide Slip No. 0840475 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for Injection and 2g Pwder for Solution for Injection or
		Infusion - PL 22805/0001, 3-5 MHRA Approved.
	Me-too status	Zetox 500mg Injection Reg. No. 053145 M/s Lahore Pharma.
	•	

	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	07.10.2020. Givii status is good.
	Decision: Approved. Registration Boregistration letter upon consideration	oard further authorized its Chairman for issuance of of satisfactory capacity assessment of manufacturing and acceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi
379.	Name and address of manufacturer/ Applicant	M/s. Perk Pharma(Pvt.) Ltd. Plot No. 197/1-B, Main Road, Industrial Estate, Gadoon Pakistan (DML No. 000857) (contract giver). Contract with M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi. (DML No.000167) contract acceptor Dry Powder Injection (Cephalosporin) Injection Section.
	Brand Name + Dosage Form + Strength	HICEF 1g IV Injection
	Composition Diagrapha Data of B. & L. & for	Each vial contains; Ceftriaxone sodium eq. to Ceftriaxone (USP)1g
	Diary No. Date of R & I & fee	Dy. No. 16950 dated 07.03.2019. Fee paid Rs. 50,000/dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for Injection and 2g Powder for Solution for Injection or Infusion - PL 22805/0001, 3-5 MHRA Approved.
	Me-too status	Rocephin IV/IM Injection 1gm Reg. No. 007014 M/s Martin Dow Karachi
	GMP status	Last inspection of M/s Mediate Pharma conducted on 09.10.2020. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Mediate Pharmaceutical (Pvt.) Ltd. Plot No. 150-151 Sector 24, Korangi Industrial Area, Karachi.	
380.	Name and address of manufacturer/ Applicant	M/s. Medisave Pharmaceuticals Plot No. 578-579, Sunder Industrial estate, sunder raiwind road Lahore. (DML No. 000681) (contract giver). Contract with M/s MTI Medical (Pvt.) Ltd. 586-587, Sunder Industrial
		estate, sunder raiwind road Lahore. (DML No.000801) contract acceptor Lyophilized Vials (General) Injection Section.
	Brand Name + Dosage Form + Strength	EPRAZIN 40mg Lyophilized injection
	Composition	Each vial contains; Esomeprazole Sodium Lyophilized equivalent to Esomeprazole40mg

I	Diary No. Date of R & I & fee	Dy. No. 14981 dated 07.03.2019. Fee paid Rs. 50,000/-
		vide slip No. 0536174 dated 05-03-2019, endorsed on
	DI I I G	06.03.2019.
	Pharmacological Group	Proton pump inhibitors,
	Towns of Forms	ATC Code: A02BC05
	Type of Form	Form-5
	Finished product Specification Pack size & Demanded Price	MTI Specifications
		As per SRO.
	Approval status of product in Reference	ESOMEPRAZOLE 40 MG POWDER FOR SOLUTION
	Regulatory Authorities	FOR INJECTION/INFUSION - PL 55035/0001 MHRA APPROVED.
	Me-too status	Nexum IV 40mg Injection Reg. No. 050651
	We-too status	M/s Getz Pharma Karachi.
	GMP status	Last inspection of M/s MTI conducted on 09.02.2022.
	OWI Status	GMP Certificate valid till 08.02.2024 is submitted
	Remarks of the Evaluator	Givir Certificate valid tili 00.02.2024 is subilifited
		specifications. Registration Board further authorized its
		on letter upon consideration of satisfactory capacity
		sting facility of M/s MTI Medical (Pvt.) Ltd. 586-587,
		ind road Lahore and submission of fee of Rs. 7,500/- for
		t specifications as per notification No.F.7-11/2012-B&A/DRAP
	dated 07-05-2021.	3 PO 11 10 11 10 11 10 11 10 11 10 11 11 11
381.	Name and address of manufacturer/	M/s. Medisave Pharmaceuticals Plot No. 578-579, Sunder
	Applicant	Industrial estate, sunder raiwind road Lahore. (DML No.
		000681) (contract giver).
		Contract with
		M/s MTI Medical (Pvt.) Ltd. 586-587, Sunder Industrial
		estate, sunder raiwind road Lahore. (DML No.000801)
		contract acceptor
		Lyophilized Vials (General) Injection Section.
	Brand Name + Dosage Form +	<u> </u>
	Brand Name + Dosage Form + Strength	Lyophilized Vials (General) Injection Section.
	9	Lyophilized Vials (General) Injection Section.
	Strength	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection
	Strength	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole40mg
	Strength	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole40mg Dy. No. 14982 dated 07.03.2019. Fee paid Rs. 50,000/-
	Strength Composition	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole40mg Dy. No. 14982 dated 07.03.2019. Fee paid Rs. 50,000/-vide slip No. 0536173 dated 05-03-2019, endorsed on
	Strength Composition Diary No. Date of R & I & fee	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole40mg Dy. No. 14982 dated 07.03.2019. Fee paid Rs. 50,000/vide slip No. 0536173 dated 05-03-2019, endorsed on 06.03.2019.
	Strength Composition	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole40mg Dy. No. 14982 dated 07.03.2019. Fee paid Rs. 50,000/-vide slip No. 0536173 dated 05-03-2019, endorsed on 06.03.2019. Proton pump inhibitors.
	Strength Composition Diary No. Date of R & I & fee Pharmacological Group	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole
	Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole
	Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole40mg Dy. No. 14982 dated 07.03.2019. Fee paid Rs. 50,000/-vide slip No. 0536173 dated 05-03-2019, endorsed on 06.03.2019. Proton pump inhibitors. ATC Code: A02BC01 Form-5 MTI Specifications
	Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole
	Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole
	Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole
	Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole
	Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole
	Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole
	Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole
	Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status	Lyophilized Vials (General) Injection Section. MEPZAN 40mg Lyophilized injection Each vial contains; Omeprazole Sodium Lyophilized equivalent to omeprazole40mg Dy. No. 14982 dated 07.03.2019. Fee paid Rs. 50,000/vide slip No. 0536173 dated 05-03-2019, endorsed on 06.03.2019. Proton pump inhibitors. ATC Code: A02BC01 Form-5 MTI Specifications As per SRO. Omeprazole 40mg Powder for Solution for Infusion (omeprazole sodium) - PL 10622/0232 MHRA APPROVED. Risek 40mg Infusion Reg. No. 024170 M/s Getz Pharma Karachi.

	Chairman for issuance of registrati assessment of manufacturing and tes Sunder Industrial estate, sunder raiw	specifications. Registration Board further authorized its on letter upon consideration of satisfactory capacity sting facility of M/s MTI Medical (Pvt.) Ltd. 586-587, ind road Lahore and submission of fee of Rs. 7,500/- for t specifications as per notification No.F.7-11/2012-B&A/DRAP
382.	Name and address of manufacturer/ Applicant	M/s. Medisave Pharmaceuticals Plot No. 578-579, Sunder Industrial estate, sunder raiwind road Lahore. (DML No. 000681) (contract giver). Contract with M/s MTI Medical (Pvt.) Ltd. 586-587, Sunder Industrial estate, sunder raiwind road Lahore. (DML No.000801) contract acceptor Lyophilized Vials (General) Injection Section.
	Brand Name + Dosage Form + Strength	P-LINE 40mg Lyophilized injection
	Composition	Each vial contains; Pantoprazole Sodium Lyophilized equivalent to pantoprazole40mg
	Diary No. Date of R & I & fee	Dy. No. 14987 dated 07.03.2019. Fee paid Rs. 50,000/-vide slip No. 0536172 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Proton pump inhibitors ATC Code: A02BC02
	Type of Form	Form-5
	Finished product Specification	MTI Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	PANTOPRAZOLE 40MG POWDER FOR SOLUTION FOR INJECTION - PL 17683/0080; UK/H/1341/001/DC MHRA Approved.
	Me-too status	Zentro Injection 045388 M/s Bosch Pharmaceutical Karachi.
	GMP status	Last inspection of M/s MTI conducted on 09.02.2022. GMP Certificate valid till 08.02.2024 is submitted
	Remarks of the Evaluator	• Innovator product contains pantoprazole as sodium sesquihydrate, in applied label sesquihydrate is not mentioned. Correction along with fee of Rs. 75000/- is required.
	Decision: Approved with innovator's specifications and following label; Each vial contains; Pantoprazole Sodium sesquihydrate Lyophilized equivalent to Pantoprazole40mg Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s MTI Medical (Pvt.) Ltd. 586-587, Sunder Industrial estate, sunder raiwind road Lahore and submission of fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
383.	Name and address of manufacturer/ Applicant	M/s. Medisave Pharmaceuticals Plot No. 578-579, Sunder Industrial estate, sunder raiwind road Lahore. (DML No. 000681) (contract giver). Contract with M/s MTI Medical (Pvt.) Ltd. 586-587, Sunder Industrial estate, sunder raiwind road Lahore. (DML No.000801) contract acceptor

		Lyophilized Vials (General) Injection Section.
	Brand Name + Dosage Form + Strength	VANCOSAVE 500mg Lyophilized Injection
	Composition	Each vial contains; Vancomycin lyophilized as HC1500mg
	Diary No. Date of R & I & fee	Dy. No. 14988 dated 07.03.2019. Fee paid Rs. 50,000/-vide slip No. 0536168 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Glycopeptide antibacterials ATC Code: J01XA01
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	VANCOMYCIN 500 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION MHRA Approved.
	Me-too status	Vancomycin Injection Reg. No. 015015 M/s Abbott Laboratories Karachi.
	GMP status	Last inspection of M/s MTI conducted on 09.02.2022. GMP Certificate valid till 08.02.2024 is submitted
	Remarks of the Evaluator	
	registration letter upon consideration of testing facility of M/s MTI Medical (Pv road Lahore.	pard further authorized its Chairman for issuance of of satisfactory capacity assessment of manufacturing and t.) Ltd. 586-587, Sunder Industrial estate, sunder raiwind
384.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Amlipine 10mg/160mg Tablet
	Composition	Each Film Coated Tablet Contains; Amlodipine as besylate USP10mg Valsartan USP160mg
	Diary No. Date of R & I & fee	Dy.No. 15465 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0825942 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers ATC Code: C09DB01
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	2x7's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	AMLODIPINE / VALSARTAN 5 MG / 80 MG, 5 MG / 160 MG AND 10 MG / 160 MG FILM-COATED TABLETS (AMLODIPINE BESILATE AND VALSARTAN) - PL 17780/0718-0720; UK/H/5856/001-3/DC MHRA APPROVED.
	Me-too status	Extor Tablet 10mg+160mg Reg. No. 054503 M/s Searle Company Ltd. Lahore.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.

	Remarks of the Evaluator	
	Decision: Approved.	
385.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Amlipine 5mg/160mg Tablet
	Composition	Each Film Coated Tablet Contains; Amlodipine as besylate USP5mg Valsartan USP160mg
	Diary No. Date of R & I & fee	Dy.No. 15466 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0825943 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers ATC Code: C09DB01
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	2x7's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	AMLODIPINE / VALSARTAN 5 MG / 80 MG, 5 MG / 160 MG AND 10 MG / 160 MG FILM-COATED TABLETS (AMLODIPINE BESILATE AND VALSARTAN) - PL 17780/0718-0720; UK/H/5856/001-3/DC
		MHRA APPROVED.
	Me-too status	Extor Tablet 5mg+160mg Reg. No. 054502 M/s Searle Company Ltd. Lahore.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator Decision: Approved.	
386.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792)
	Brand Name + Dosage Form + Strength	Tablet (general) Section. Amlipine 5mg/80mg Tablet
	Composition	Each Film Coated Tablet Contains; Amlodipine as besylate USP5mg Valsartan USP80mg
	Diary No. Date of R & I & fee	Dy.No. 15428 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0801849 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers ATC Code: C09DB01
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	2x7's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	AMLODIPINE / VALSARTAN 5 MG / 80 MG, 5 MG / 160 MG AND 10 MG / 160 MG FILM-COATED TABLETS (AMLODIPINE BESILATE AND
		TADED TO (MILCOUR IND DESIDATE AND

		VALSARTAN) - PL 17780/0718-0720; UK/H/5856/001- 3/DC
	26	MHRA APPROVED.
	Me-too status	Extor Tablet 5mg+80mg Reg. No. 054501 M/s Searle Company Ltd. Lahore.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
387.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	SOCALM 100mg Tablet
	Composition	Each Film Coated Tablet Contains; Quetiapine as fumarate100mg
	Diary No. Date of R & I & fee	Dy.No. 15414 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844323 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH04
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	QUETIAPINE 25MG, 100MG, 150MG, 200MG AND 300MG FILM-COATED TABLETS - PL 24668/0163-7 MHRA APPROVED.
	Me-too status	Qusel 100mg Tablet Reg. no. 037685 M/s Hilton Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
388.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	SOCALM 25mg Tablet
	Composition	Each Film Coated Tablet Contains; Quetiapine as fumarate25mg
	Diary No. Date of R & I & fee	Dy.No. 15412 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844325 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH04
	Pharmacological Group Type of Form	
		ATC Code: N05AH04
	Type of Form	ATC Code: N05AH04 Form-5
	Type of Form Finished product Specification	ATC Code: N05AH04 Form-5 USP Specifications

		M/s Hilton Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is
		good.
	Remarks of the Evaluator	
	Decision: Approved.	
389.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792)
	Brand Name + Dosage Form + Strength	Tablet (general) Section. SOCALOM 150mg Tablet
	Composition	Each Tablet Contains; Quetiapine as fumarate150mg
	Diary No. Date of R & I & fee	Dy.No. 15472 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0825949 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH04
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's. 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	QUETIAPINE 25MG, 100MG, 150MG, 200MG AND 300MG FILM-COATED TABLETS - PL 24668/0163-7 MHRA APPROVED.
	Me-too status	Could not be verified for immediate release tablet.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	Product approved in RRA is film coated and me-too products are XR. Clarification or correction along with fee is required.
	Decision: Deferred for evidence of applie too status) alongwith registration number	d formulation/drug already approved by DRAP (generic / me-
390.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	DEPRIN 75mg Tablet
	Composition	Each Film Coated Tablet Contains; Bupropion hydrochloride USP75mg
	Diary No. Date of R & I & fee	Dy.No. 15430 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844389 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antidepressants ATC Code: N06AX12
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	BUPROPION HYDROCHLORIDE 75MG ORAL TABLET, APOTEX INC USFDA APPROVED.
	Me-too status	Smokik 75mg Tablet 75mg Reg. No. 035774 M/s Hilton Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is

		good.
	Remarks of the Evaluator	
	Decision: Approved.	
391.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	DEPRIN XL 150mg Tablet
	Composition	Each Film Coated Extended Release Tablet Contains; Bupropion hydrochloride USP150mg
	Diary No. Date of R & I & fee	Dy.No. 15442 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0811900 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antidepressants ATC Code: N06AX12
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	ZYBAN 150 MG PROLONGED RELEASE TABLETS MHRA APPROVED.
	Me-too status	Ropion Tablet 150mg Reg. No. 037112 M/s martin Dow Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
392.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	OZINE 5mg Tablet
	Composition	Each Film Coated Tablet Contains; Olanzapine (USP)5mg
	Diary No. Date of R & I & fee	Dy.No. 15487 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 1901910 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH03
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	OLANZAPINE 2.5 MG, 5 MG, 7.5 MG, 10 MG, 15 MG AND 20 MG TABLETS - PL 32854/0015-20 (FILM COATED) MHRA APPROVED.
	Me-too status	Lepinza 5mg Tablet Reg. No. 061302 M/s Nexus Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	

393.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	OZINE 10mg Tablet
	Composition	Each Film Coated Tablet Contains; Olanzapine (USP)10mg
	Diary No. Date of R & I & fee	Dy.No. 15485 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 1901908 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH03
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	OLANZAPINE 2.5 MG, 5 MG, 7.5 MG, 10 MG, 15 MG AND 20 MG TABLETS - PL 32854/0015-20 (FILM COATED) MHRA APPROVED.
	Me-too status	Lepinza 10mg Tablet Reg. No. 061303 M/s Nexus Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
394.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	OZINE-F 6mg+25mg Capsule
	Composition	Each capsule contains; Olanzapine (USP)6mg Fluoxetine as Hydrochloride (USP)25mg
	Diary No. Date of R & I & fee	Dy.No. 15453 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844511 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Antidepressent combination with antipsychotic.
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 14's, 30's. As per SRO.
	Approval status of product in Reference	SYMBYAX CAPSULES
	Regulatory Authorities	USFDA APPROVED.
	Me-too status	Co-depricap 6/25 capsule Reg. No. 076135 M/s Nabiqasim Industries Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
395.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792)
		Capsule (general) Section.

	Brand Name + Dosage Form + Strength	NEUGABA 100mg Capsule
	Composition	Each capsule contains;
	Diary No. Date of R & I & fee	Pregabalin (USP)100mg Dy.No. 15451 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844509 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Gabapentinoids ATC Code: N02BF02
	Type of Form	Form-5
	Finished product Specification	In-House
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PREGABALIN NOUMED 25, 50, 75, 100, 150, 200, 225 AND 300MG CAPSULES, HARD (PREGABALIN) - PL 44041/0065-0072
		MHRA APPROVED.
	Me-too status	Gabica 100 mg Capsule Reg. No. 047366 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
		tions. or correction/pre-approval change in product specifications as AP dated 07-05-2021, before issuance of registration letter.
396.	Name and address of manufacturer/	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial
	Applicant	Triangle Kahuta Road, Islamabad (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	NEUGABA 50mg Capsule
	Composition	Each capsule contains; Pregabalin (USP)50mg
	Diary No. Date of R & I & fee	Dy.No. 15450 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844508 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Gabapentinoids ATC Code: N02BF02
	Type of Form	Form-5
	Finished product Specification	In-House
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PREGABALIN NOUMED 25, 50, 75, 100, 150, 200, 225 AND 300MG CAPSULES, HARD (PREGABALIN) - PL 44041/0065-0072 MHRA APPROVED.
	Me-too status	Gabica 50 mg Capsule Reg. No. 048725 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	5000.
	Decision: Approved with BP Specificat	tions.
	The firm shall submit fee of Rs. 7,500/- fo	or correction/pre-approval change in product specifications as AP dated 07-05-2021, before issuance of registration letter.

397.	37 1 11 6 6 6 /	36/ 31 / 1 8/ 21 / 1 / 1 / 1 / 1 / 1 / 1
	Name and address of manufacturer/	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial
	Applicant	Triangle Kahuta Road, Islamabad (DML No. 000792)
		Capsule (general) Section.
	Brand Name + Dosage Form +	NEUGABA 75mg Capsule
	Strength	
	Composition	Each capsule contains;
		Pregabalin (USP)75mg
	Diary No. Date of R & I & fee	Dy.No. 15452 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844510 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Gabapentinoids ATC Code: N02BF02
	Type of Form	Form-5
	Finished product Specification	In-House
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference	PREGABALIN NOUMED 25, 50, 75, 100, 150, 200, 225
	Regulatory Authorities	AND 300MG CAPSULES, HARD (PREGABALIN) - PL 44041/0065-0072
		MHRA APPROVED.
	Me-too status	Gabica 75 mg Capsule Reg. No. 047365
		M/s Getz Pharma (Pvt) Ltd Karachi
	GMP status	Last inspection conducted on 29.04.2021. GMP status is
		good.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifica	tions.
	The firm shall submit fee of Rs. 7,500/- fo	or correction/pre-approval change in product specifications as AP dated 07-05-2021, before issuance of registration letter.
398.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
		TELL DO LEE LE LE LE CONTROL CONTROL
		Kahuta Road, Islamabad (DML No. 000792)
		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Tablet (general) Section. NEBINOR 2.5mg Tablet
	Brand Name + Dosage Form + Strength Composition	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains;
	Composition	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg
		Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip
	Composition Diary No. Date of R & I & fee	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019
	Composition	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip
	Composition Diary No. Date of R & I & fee	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019 Beta blocking agents, selective
	Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019 Beta blocking agents, selective ATC Code: C07AB12
	Composition Diary No. Date of R & I & fee Pharmacological Group	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019 Beta blocking agents, selective ATC Code: C07AB12 Form-5
	Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019 Beta blocking agents, selective ATC Code: C07AB12 Form-5 In-House
	Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019 Beta blocking agents, selective ATC Code: C07AB12 Form-5 In-House 10's, 14's. As per SRO. NEBIVOLOL 2.5, 5 & 10MG TABLETS - PL 44041/0050-52
	Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019 Beta blocking agents, selective ATC Code: C07AB12 Form-5 In-House 10's, 14's. As per SRO. NEBIVOLOL 2.5, 5 & 10MG TABLETS - PL 44041/0050-52 MHRA APPROVED.
	Composition Diary No. Date of R & I & 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	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019 Beta blocking agents, selective ATC Code: C07AB12 Form-5 In-House 10's, 14's. As per SRO. NEBIVOLOL 2.5, 5 & 10MG TABLETS - PL 44041/0050-52 MHRA APPROVED. Nebix 2.5mg Tablet Reg. No. 062776
	Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019 Beta blocking agents, selective ATC Code: C07AB12 Form-5 In-House 10's, 14's. As per SRO. NEBIVOLOL 2.5, 5 & 10MG TABLETS - PL 44041/0050-52 MHRA APPROVED. Nebix 2.5mg Tablet Reg. No. 062776 M/s Highnoon Laboratories Lahore.
	Composition Diary No. Date of R & I & 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 with Innovator's specorrection/pre-approval change in product status	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019 Beta blocking agents, selective ATC Code: C07AB12 Form-5 In-House 10's, 14's. As per SRO. NEBIVOLOL 2.5, 5 & 10MG TABLETS - PL 44041/0050-52 MHRA APPROVED. Nebix 2.5mg Tablet Reg. No. 062776 M/s Highnoon Laboratories Lahore. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP
399.	Composition Diary No. Date of R & I & 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 with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registrar	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019 Beta blocking agents, selective ATC Code: C07AB12 Form-5 In-House 10's, 14's. As per SRO. NEBIVOLOL 2.5, 5 & 10MG TABLETS - PL 44041/0050-52 MHRA APPROVED. Nebix 2.5mg Tablet Reg. No. 062776 M/s Highnoon Laboratories Lahore. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter.
399.	Composition Diary No. Date of R & I & 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 with Innovator's specorrection/pre-approval change in product status	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019 Beta blocking agents, selective ATC Code: C07AB12 Form-5 In-House 10's, 14's. As per SRO. NEBIVOLOL 2.5, 5 & 10MG TABLETS - PL 44041/0050-52 MHRA APPROVED. Nebix 2.5mg Tablet Reg. No. 062776 M/s Highnoon Laboratories Lahore. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
399.	Composition Diary No. Date of R & I & 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 with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registrar	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019 Beta blocking agents, selective ATC Code: C07AB12 Form-5 In-House 10's, 14's. As per SRO. NEBIVOLOL 2.5, 5 & 10MG TABLETS - PL 44041/0050-52 MHRA APPROVED. Nebix 2.5mg Tablet Reg. No. 062776 M/s Highnoon Laboratories Lahore. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792)
399.	Composition Diary No. Date of R & I & 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 with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registrar	Tablet (general) Section. NEBINOR 2.5mg Tablet Each uncoated tablet contains; Nebivolol as Hydrochloride (USP)2.5mg Dy.No. 15460 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844518 dated 05.03.2019, endorsed on 06.03.2019 Beta blocking agents, selective ATC Code: C07AB12 Form-5 In-House 10's, 14's. As per SRO. NEBIVOLOL 2.5, 5 & 10MG TABLETS - PL 44041/0050-52 MHRA APPROVED. Nebix 2.5mg Tablet Reg. No. 062776 M/s Highnoon Laboratories Lahore. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle

		Escitalopram as oxalate10mg
	Diary No. Date of R & I & fee	Dy.No. 15417 dated 07-03-2019; Fee Rs.20,000 paid vide slip
	Diary No. Date of R & T & Tee	No. 0844320 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Tharmacorogical Group	ATC Code: N06AB10
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference	Escitalopram 5, 10 & 20mg Film-Coated Tablets (PL
	Regulatory Authorities	36390/0149-51; UK/H/5394/001-3/DC)
		MHRA Approved.
	Me-too status	Cipralex Film-Coated Tablet 10mg Reg. No. 028467
		M/s Lundbeck Pakistan (Pvt.) Ltd. Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
400.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
100.	Traine and address of manufacturen rippireant	Kahuta Road, Islamabad (DML No. 000792)
		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	N-PRAM 10mg Tablet
	Composition	Each film coated tablet contains;
	- Confession	Escitalopram as oxalate10mg
	Diary No. Date of R & I & fee	Dy.No. 15417 dated 07-03-2019; Fee Rs.20,000 paid vide slip
		No. 0844320 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
		ATC Code: N06AB10
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference	Escitalopram 5, 10 & 20mg Film-Coated Tablets (PL
	Regulatory Authorities	36390/0149-51; UK/H/5394/001-3/DC)
		MHRA Approved.
	Me-too status	Cipralex Film-Coated Tablet 10mg Reg. No. 028467
		M/s Lundbeck Pakistan (Pvt.) Ltd. Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
401.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
		Kahuta Road, Islamabad (DML No. 000792)
		Capsule (general) Section.
	Brand Name + Dosage Form + Strength	DAXUM 60mg Capsule
	Composition	Each capsule contains;
		Duloxetine as enteric coated pellets 17% (USP)60mg
	Diary No. Date of R & I & fee	Dy.No. 15449 dated 07-03-2019; Fee Rs.20,000 paid vide slip
		No. 0844507 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antidepressants
		ATC Code: N06AX21
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference	DULOXETINE 60 MG GASTRO-RESISTANT CAPSULES,
	Regulatory Authorities	HARD - PL 49445/0097
		MHRA Approved.
	Me-too status	Lyta 60mg Capsule Reg. No. 066918
	av m	M/s Getz Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.

	Remarks of the Evaluator	Source of pellets is required.
		it source of pellets along with stability studies data, GMP
	certificate of supplier and differential fee in	case of import of pellets before issuance of registration letter.
402.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
		Kahuta Road, Islamabad (DML No. 000792)
		Capsule (general) Section.
	Brand Name + Dosage Form + Strength	DAXUM 30mg Capsule
	Composition	Each capsule contains;
		Duloxetine as enteric coated pellets 17% (USP)30mg
	Diary No. Date of R & I & fee	Dy.No. 15448 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844506 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antidepressants ATC Code: N06AX21
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference	DULOXETINE 30 MG GASTRO-RESISTANT CAPSULES,
	Regulatory Authorities	HARD - PL 49445/0095
		MHRA Approved.
	Me-too status	Lyta 30mg Capsule Reg. No. 066917
		M/s Getz Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	Source of pellets is required.
		it source of pellets along with stability studies data, GMP
		case of import of pellets before issuance of registration letter.
403.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
105.	Traine and address of manufacturer/ reprireme	Kahuta Road, Islamabad (DML No. 000792)
		Tablet (general) Section.
	Brand Nama Dasaga Farm Strangth	LACOMIDE 50mg Tablet
	Brand Name + Dosage Form + Strength	Each film coated tablet contains;
	Composition	· ·
		Lacosamide50mg
	Diary No. Date of R & I & fee	Dy.No. 15432 dated 07-03-2019; Fee Rs.20,000 paid vide slip
	Diary No. Date of R & I & Ice	No. 08444400 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antiepileptics
	Tharmacological Group	ATC Code: N03AX18
	Type of Form	Form-5
	Type of Form	In-House
	Finished product Specification	
	Pack size & Demanded Price	10's, 14's. As per SRO.
	Approval status of product in Reference	LACOSAMIDE AMAROX 50 MG FILM-COATED
	Approval status of product in Reference Regulatory Authorities	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081
	Regulatory Authorities	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved.
		LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved. Lacoste 50mg Tablet Reg. No. 086629
	Regulatory Authorities Me-too status	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved. Lacoste 50mg Tablet Reg. No. 086629 M/s Scilife Karachi.
	Regulatory Authorities Me-too status GMP status	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved. Lacoste 50mg Tablet Reg. No. 086629
	Regulatory Authorities Me-too status GMP status Remarks of the Evaluator	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved. Lacoste 50mg Tablet Reg. No. 086629 M/s Scilife Karachi. Last inspection conducted on 29.04.2021. GMP status is good.
	Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's spe	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved. Lacoste 50mg Tablet Reg. No. 086629 M/s Scilife Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for
	Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved. Lacoste 50mg Tablet Reg. No. 086629 M/s Scilife Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP
404	Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registra	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved. Lacoste 50mg Tablet Reg. No. 086629 M/s Scilife Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter.
404.	Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved. Lacoste 50mg Tablet Reg. No. 086629 M/s Scilife Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
404.	Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registra	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved. Lacoste 50mg Tablet Reg. No. 086629 M/s Scilife Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792)
404.	Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registra Name and address of manufacturer/ Applicant	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved. Lacoste 50mg Tablet Reg. No. 086629 M/s Scilife Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section.
404.	Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registra Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved. Lacoste 50mg Tablet Reg. No. 086629 M/s Scilife Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. LACOMIDE 100mg Tablet
404.	Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registra Name and address of manufacturer/ Applicant	LACOSAMIDE AMAROX 50 MG FILM-COATED TABLETS - PL 49445/0081 MHRA Approved. Lacoste 50mg Tablet Reg. No. 086629 M/s Scilife Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section.

	Diary No. Date of R & I & fee	Dy.No. 15431 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844399 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antiepileptics ATC Code: N03AX18
	Type of Form	Form-5
	Finished product Specification	In-House
	Pack size & Demanded Price	14's. As per SRO.
		LACOSAMIDE AMAROX 100 MG FILM-COATED
	Approval status of product in Reference	
	Regulatory Authorities	TABLETS - PL 49445/0082
	76	MHRA Approved.
	Me-too status	Lacoste 100mg Tablet Reg. No. 086630 M/s Scilife Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's spe	cifications. The firm shall submit fee of Rs. 7,500/- for
	correction/pre-approval change in product a dated 07-05-2021, before issuance of registra	specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter.
405.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
	Table 1 and	Kahuta Road, Islamabad (DML No. 000792)
		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	FESAT 40mg Tablet
	Composition	Each Film Coated Tablet Contains;
	Composition	· ·
	D' N D (CD 0 I 0 C	Febuxostat40mg
	Diary No. Date of R & I & fee	Dy.No. 16411 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 1901933 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Preparations inhibiting uric acid production ATC Code: M04AA03
	Type of Form	Form-5
	Linished product Specification	In_House
	Finished product Specification	In-House
	Pack size & Demanded Price	20's, 30's. As per SRO.
	Pack size & Demanded Price Approval status of product in Reference	20's, 30's. As per SRO. Uloric tablets 40 mg.
	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved.
	Pack size & Demanded Price Approval status of product in Reference	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033
	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi.
	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033
	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi.
	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi.
	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product status	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP
	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's spe correction/pre-approval change in product dated 07-05-2021, before issuance of registrations.	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter.
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product status	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's spe correction/pre-approval change in product dated 07-05-2021, before issuance of registrations.	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter.
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's spe correction/pre-approval change in product dated 07-05-2021, before issuance of registrations.	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's spe correction/pre-approval change in product dated 07-05-2021, before issuance of registrations.	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792)
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registrate Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. FESAT 80mg Tablet
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registration. Name and address of manufacturer/ Applicant	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. FESAT 80mg Tablet Each Film Coated Tablet Contains;
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registration Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. FESAT 80mg Tablet Each Film Coated Tablet Contains; Febuxostat80mg
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registrate Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. FESAT 80mg Tablet Each Film Coated Tablet Contains;
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registration Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. FESAT 80mg Tablet Each Film Coated Tablet Contains; Febuxostat80mg Dy.No. 15439 dated 07-03-2019; Fee Rs.20,000 paid vide slip
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registrate Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. FESAT 80mg Tablet Each Film Coated Tablet Contains; Febuxostat80mg Dy.No. 15439 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0811897 dated 06.03.2019, endorsed on 07.03.2019
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registrate Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. FESAT 80mg Tablet Each Film Coated Tablet Contains; Febuxostat80mg Dy.No. 15439 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0811897 dated 06.03.2019, endorsed on 07.03.2019 Preparations inhibiting uric acid production
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registration Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. FESAT 80mg Tablet Each Film Coated Tablet Contains; Febuxostat80mg Dy.No. 15439 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0811897 dated 06.03.2019, endorsed on 07.03.2019 Preparations inhibiting uric acid production ATC Code: M04AA03
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registrate Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification	20's, 30's. As per SRO. Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. FESAT 80mg Tablet Each Film Coated Tablet Contains; Febuxostat80mg Dy.No. 15439 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0811897 dated 06.03.2019, endorsed on 07.03.2019 Preparations inhibiting uric acid production ATC Code: M04AA03 Form-5 In-House
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registrate Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. FESAT 80mg Tablet Each Film Coated Tablet Contains; Febuxostat80mg Dy.No. 15439 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0811897 dated 06.03.2019, endorsed on 07.03.2019 Preparations inhibiting uric acid production ATC Code: M04AA03 Form-5 In-House 20's, 30's. As per SRO.
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product stated 07-05-2021, before issuance of registrated Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference	Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. FESAT 80mg Tablet Each Film Coated Tablet Contains; Febuxostat80mg Dy.No. 15439 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0811897 dated 06.03.2019, endorsed on 07.03.2019 Preparations inhibiting uric acid production ATC Code: M04AA03 Form-5 In-House 20's, 30's. As per SRO. Uloric tablets 80 mg.
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product dated 07-05-2021, before issuance of registrate Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. FESAT 80mg Tablet Each Film Coated Tablet Contains; Febuxostat80mg Dy.No. 15439 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0811897 dated 06.03.2019, endorsed on 07.03.2019 Preparations inhibiting uric acid production ATC Code: M04AA03 Form-5 In-House 20's, 30's. As per SRO. Uloric tablets 80 mg. USFDA Approved.
406.	Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status GMP status Remarks of the Evaluator Decision: Approved with Innovator's specorrection/pre-approval change in product stated 07-05-2021, before issuance of registrated Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference	Uloric tablets 40 mg. FDA Approved. Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter. M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section. FESAT 80mg Tablet Each Film Coated Tablet Contains; Febuxostat80mg Dy.No. 15439 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0811897 dated 06.03.2019, endorsed on 07.03.2019 Preparations inhibiting uric acid production ATC Code: M04AA03 Form-5 In-House 20's, 30's. As per SRO. Uloric tablets 80 mg.

	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	,
		cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter.
407.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	MIRNTE 30mg Tablet
	Composition	Each Film Coated Tablet Contains; Mirtazapine USP30mg
	Diary No. Date of R & I & fee	Dy.No. 15461 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844519 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Other antidepressants ATC Code: N06AX11
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Mirtazapine 15 mg, 30 mg and 45 mg film-coated tablets - PL 28444/0097-9 MHRA Approved.
	Me-too status	Mezeron 30mg Tablet Reg. No. 026397 M/s OBS Pakistan (Pvt.) Ltd. Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
408.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	OLMEZEST 20mg/5mg Tablet
	Composition	Each Film Coated Tablet Contains;
	-	Amlodipine as Besylate USP5mg
	Diary No. Date of R & I & fee	Olmesartan medoximil USP20mg Dy.No. 15490 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 1901913 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers.
	Towns of Forms	ATC Code: C09DB02
	Type of Form Finished product Specification	Form-5 In-House Specs
	Pack size & Demanded Price	20's. As per SRO.
	Approval status of product in Reference	Olmesartan medoxomil and Amlodipine 20mg/5mg, 40mg/5mg
	Regulatory Authorities	& 40mg/10mg film-coated tablets PL 51718/0032-0034 MHRA Approved.
	Me-too status	Baritec-A 20/5mg Tablet Reg. No. 081442 M/s Barrett Hodgson Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
		cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter.
409.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
		Kahuta Road, Islamabad (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	OLMEZEST 40mg/5mg Tablet
	Composition	Each Film Coated Tablet Contains;

		Amlodipine as Besylate USP5mg
		Olmesartan medoximil USP40mg
	Diary No. Date of R & I & fee	Dy.No. 15488 dated 07-03-2019; Fee Rs.20,000 paid vide slip
	Diameter 1 Course	No. 1901911 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers.
		ATC Code: C09DB02
	Type of Form	Form-5
	Finished product Specification	In-House Specs
	Pack size & Demanded Price	20's. As per SRO.
	Approval status of product in Reference	Olmesartan medoxomil and Amlodipine 20mg/5mg, 40mg/5mg
	Regulatory Authorities	& 40mg/10mg film-coated tablets PL 51718/0032-0034 MHRA Approved.
	Me-too status	Baritec-A 40/5mg Tablet Reg. No. 081443
	We-too status	M/s Barrett Hodgson Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	Last inspection conducted on 25.0 1.2021. Offir status is good.
		cifications. The firm shall submit fee of Rs. 7,500/- for
		specifications as per notification No.F.7-11/2012-B&A/DRAP
410.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
		Kahuta Road, Islamabad (DML No. 000792)
		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	OLMEZEST 20mg/10mg Tablet
	Composition	Each Film Coated Tablet Contains;
		Amlodipine as Besylate USP10mg
		Olmesartan medoximil USP20mg
	Diary No. Date of R & I & fee	Dy.No. 15489 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 1901912 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel
		blockers.
		ATC Code: C09DB02
	Type of Form	Form-5
	Finished product Specification	In-House Specs
	Pack size & Demanded Price	20's. As per SRO.
	Approval status of product in Reference	AZOR 10mg/20mg Tablet
	Regulatory Authorities Me-too status	USFDA Approved. Omsana-AM 10/20 Tablet Reg. No. 058559
	We-too status	M/s Hilton Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	Last hispection conducted on 27.04.2021. Givin status is good.
		cifications. The firm shall submit fee of Rs. 7,500/- for
		specifications as per notification No.F.7-11/2012-B&A/DRAP
	dated 07-05-2021, before issuance of registrate	
411.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
		Kahuta Road, Islamabad (DML No. 000792)
		Tablet (general) Section.
1		
	Brand Name + Dosage Form + Strength	PAROXID CR Tablet 12.5mg
	Brand Name + Dosage Form + Strength Composition	PAROXID CR Tablet 12.5mg Each enteric film coated controlled release tablet contains;
	Composition	PAROXID CR Tablet 12.5mg Each enteric film coated controlled release tablet contains; Paroxetine as Hydrochloride hemihydrate USP.12.5mg
	<u> </u>	PAROXID CR Tablet 12.5mg Each enteric film coated controlled release tablet contains; Paroxetine as Hydrochloride hemihydrate USP.12.5mg Dy.No. 15421 dated 07-03-2019; Fee Rs.20,000 paid vide slip
	Composition Diary No. Date of R & I & fee	PAROXID CR Tablet 12.5mg Each enteric film coated controlled release tablet contains; Paroxetine as Hydrochloride hemihydrate USP.12.5mg Dy.No. 15421 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844316 dated 05.03.2019, endorsed on 06.03.2019
	Composition	PAROXID CR Tablet 12.5mg Each enteric film coated controlled release tablet contains; Paroxetine as Hydrochloride hemihydrate USP.12.5mg Dy.No. 15421 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844316 dated 05.03.2019, endorsed on 06.03.2019 Selective serotonin reuptake inhibitors
	Composition Diary No. Date of R & I & fee Pharmacological Group	PAROXID CR Tablet 12.5mg Each enteric film coated controlled release tablet contains; Paroxetine as Hydrochloride hemihydrate USP.12.5mg Dy.No. 15421 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844316 dated 05.03.2019, endorsed on 06.03.2019 Selective serotonin reuptake inhibitors ATC Code: N06AB05
	Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form	PAROXID CR Tablet 12.5mg Each enteric film coated controlled release tablet contains; Paroxetine as Hydrochloride hemihydrate USP.12.5mg Dy.No. 15421 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844316 dated 05.03.2019, endorsed on 06.03.2019 Selective serotonin reuptake inhibitors ATC Code: N06AB05 Form-5
	Composition Diary No. Date of R & I & fee Pharmacological Group	PAROXID CR Tablet 12.5mg Each enteric film coated controlled release tablet contains; Paroxetine as Hydrochloride hemihydrate USP.12.5mg Dy.No. 15421 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844316 dated 05.03.2019, endorsed on 06.03.2019 Selective serotonin reuptake inhibitors ATC Code: N06AB05

	Approval status of product in Reference	PAXIL CR 12.5mg tablet Extended release
	Regulatory Authorities	USFDA Approved.
	Me-too status	Seroxat CR Tablet 12.5mg Reg. No. 043058 M/s GSK Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
412.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
712.	Traine and address of manufacture? Applicant	Kahuta Road, Islamabad (DML No. 000792)
		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	PAROXID CR Tablet 37.5mg
	Composition	Each enteric film coated controlled release tablet contains; Paroxetine as Hydrochloride hemihydrate USP.37.5mg
	Diary No. Date of R & I & fee	Dy.No. 15419 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844318 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code: N06AB05
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	30's. As per SRO.
	Approval status of product in Reference	PAXIL CR 37.5mg tablet Extended release
	Regulatory Authorities	USFDA Approved.
	Me-too status	Paraxyl CR Tablet 37.5mg Reg. No. 060323
	Me-too status	M/s GSK Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
		Last hispection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
413.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792)
		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	PAROXID CR Tablet 25mg
	Composition	Each enteric film coated controlled release tablet contains; Paroxetine as Hydrochloride hemihydrate USP.25mg
	Diary No. Date of R & I & fee	Dy.No. 15420 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844317 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Thatmacorogical Group	ATC Code: N06AB05
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	30's. As per SRO.
	Approval status of product in Reference	PAXIL CR 25mg tablet Extended release
		USFDA Approved.
	Regulatory Authorities Me-too status	Zara 25mg Reg. No. 069192
	We-too status	M/s Shrooq Pharma Lahore.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	Last hispection conducted on 27.04,2021. Givin status is good.
	Decision: Approved.	
414.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad (DML No. 000792)
	D 111 D E C 4	Ampoule (general) Section.
	Brand Name + Dosage Form + Strength	Aquanor 10ml WFI
	Composition	Each 10ml Ampoule Contain; Water for injection10ml
	Diary No. Date of R & I & fee	Dy.No. 16425 dated 07-03-2019; Fee Rs.20,000 paid vide slip
	Diary INO. Date of K & I & Ice	No. 1901949 dated 06.03.2019, endorsed on 07.03.2019

	D1	NIA
	Pharmacological Group	NA .
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	NA
	Regulatory Authorities	
	Me-too status	NA
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
415.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
		Kahuta Road, Islamabad (DML No. 000792)
		Ampoule (general) Section.
	Brand Name + Dosage Form + Strength	Aquanor 10ml WFI
	Composition	Each 10ml Ampoule Contain;
		Water for injection10ml
	Diary No. Date of R & I & fee	Dy.No. 16425 dated 07-03-2019; Fee Rs.20,000 paid vide slip
		No. 1901949 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	NA
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Sterilised Water for Injections - PL 01502/0069
	Regulatory Authorities	MHRA Approved.
	Me-too status	Sterile water for injection 10ml Reg. No. 053043
	We-too status	M/s Getz Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	Last hispection conducted on 27.04.2021. Givin status is good.
	Decision: Approved.	
416.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
		Kahuta Road, Islamabad (DML No. 000792)
		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	VIOMET 50mg/1000mg Tablet
	Composition	Each film coated tablet contains Contain;
		Vidagliptin50mg
		Metformin HCl USP1000mg
	Diary No. Date of R & I & fee	
	Diary No. Date of R & I & fee	Metformin HCl USP1000mg
	Diary No. Date of R & I & fee Pharmacological Group	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip
		Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019
		Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose
	Pharmacological Group	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs,
	Pharmacological Group Type of Form	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08
	Pharmacological Group	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08 Form-5 In-House
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08 Form-5 In-House As per SRO.
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08 Form-5 In-House As per SRO. VILDAGLIPTIN/METFORMIN 50 MG/1000 MG FILM-
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08 Form-5 In-House As per SRO. VILDAGLIPTIN/METFORMIN 50 MG/1000 MG FILM-COATED TABLETS
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08 Form-5 In-House As per SRO. VILDAGLIPTIN/METFORMIN 50 MG/1000 MG FILM-COATED TABLETS MHRA Approved.
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08 Form-5 In-House As per SRO. VILDAGLIPTIN/METFORMIN 50 MG/1000 MG FILM-COATED TABLETS MHRA Approved. Velon-M Tablet Reg. No. 084692
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08 Form-5 In-House As per SRO. VILDAGLIPTIN/METFORMIN 50 MG/1000 MG FILM-COATED TABLETS MHRA Approved. Velon-M Tablet Reg. No. 084692 M/s Genix Pharma Karachi.
	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	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08 Form-5 In-House As per SRO. VILDAGLIPTIN/METFORMIN 50 MG/1000 MG FILM-COATED TABLETS MHRA Approved. Velon-M Tablet Reg. No. 084692
	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	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08 Form-5 In-House As per SRO. VILDAGLIPTIN/METFORMIN 50 MG/1000 MG FILM-COATED TABLETS MHRA Approved. Velon-M Tablet Reg. No. 084692 M/s Genix Pharma Karachi. Last inspection conducted on 29.04.2021. GMP status is good.
	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 with Innovator's specification	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08 Form-5 In-House As per SRO. VILDAGLIPTIN/METFORMIN 50 MG/1000 MG FILM-COATED TABLETS MHRA Approved. Velon-M Tablet Reg. No. 084692 M/s Genix Pharma Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for
	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 with Innovator's specorrection/pre-approval change in product states.	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08 Form-5 In-House As per SRO. VILDAGLIPTIN/METFORMIN 50 MG/1000 MG FILM-COATED TABLETS MHRA Approved. Velon-M Tablet Reg. No. 084692 M/s Genix Pharma Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP
417	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 with Innovator's specification correction/pre-approval change in product of dated 07-05-2021, before issuance of registrates	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08 Form-5 In-House As per SRO. VILDAGLIPTIN/METFORMIN 50 MG/1000 MG FILM-COATED TABLETS MHRA Approved. Velon-M Tablet Reg. No. 084692 M/s Genix Pharma Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP tion letter.
417.	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 with Innovator's specorrection/pre-approval change in product states.	Metformin HCl USP1000mg Dy.No. 15416 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0844321 dated 05.03.2019, endorsed on 06.03.2019 Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD08 Form-5 In-House As per SRO. VILDAGLIPTIN/METFORMIN 50 MG/1000 MG FILM-COATED TABLETS MHRA Approved. Velon-M Tablet Reg. No. 084692 M/s Genix Pharma Karachi. Last inspection conducted on 29.04.2021. GMP status is good. cifications. The firm shall submit fee of Rs. 7,500/- for specifications as per notification No.F.7-11/2012-B&A/DRAP

		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	VIOMET 50mg/850mg Tablet
	Composition	Each film coated tablet contains Contain;
	Composition	Vidagliptin50mg
	Diama Na Data af D O I O fac	Metformin HCl USP850mg
	Diary No. Date of R & I & fee	Dy.No. 15410 dated 07-03-2019; Fee Rs.20,000 paid vide slip
	DI 1 : 1 C	No. 0844327 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Drugs used in diabetes, combinations of oral blood glucose
		lowering drugs,
	The state of the s	ATC code: A10BD08
	Type of Form	Form-5
	Finished product Specification	In-House
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	VILDAGLIPTIN/METFORMIN 50 MG/850 MG FILM-
	Regulatory Authorities	COATED TABLETS
		MHRA Approved.
	Me-too status	Velon-M Tablet Reg. No. 074866
		M/s Genix Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
		cifications. The firm shall submit fee of Rs. 7,500/- for
		specifications as per notification No.F.7-11/2012-B&A/DRAP
	dated 07-05-2021, before issuance of registrate	
418.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle
		Kahuta Road, Islamabad (DML No. 000792)
		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	SIOMET 50mg/1000mg Tablet
	Composition	Each film coated tablet contains Contain;
		Sitagliptin phosphate monohydrate50mg
		Metformin HCl1000mg
	Diary No. Date of R & I & fee	Dy. No. 15411 dated 07-03-2019; Fee Rs.20,000 paid vide slip
		No. 0844326 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
		ATC Code: A10BD07
	Type of Form	Form-5
	Finished product Specification	In-House
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Janumet Tablets
	Regulatory Authorities	MHRA Approved.
	Me-too status	Treviamet 50mg 1000mg Tablet Reg. No. 055444
		M/s Getz Pharma Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's spe	cifications. The firm shall submit fee of Rs. 7,500/- for
		specifications as per notification No.F.7-11/2012-B&A/DRAP
	dated 07-05-2021, before issuance of registra	
419.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S3, National Industrial
		Zone, Rawat, Islamabad. (DML No.000551)
		Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tranex Capsule 250mg
	Composition	Each capsule contains;
		Tranexamic Acid250mg
	Diary No. Date of R & I & fee	Dy. No. 16384 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
		No. 1900233 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	B02AA02 Amino acids
	Type of Form	Form-5

	Finished product Specification	BP Specifications (couldn't be found in BP, available in JP)
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed in capsule dosage form
	Me-too status	Melaxic 250mg Capsule Reg. No. 113136 M/s Crystolite Pharmaceuticals.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Evidence of RRA approval of product in Capsule dosage form is required.
	 Decision: Deferred for following; Evidence of approval of applied form were adopted by the Registration Boa Section approval letter. Latest GMP inspection report/ certifities 	
420.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S3, National Industrial
	Tr-	Zone, Rawat, Islamabad. (DML No.000551)
		Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tranex Capsule 500mg
	Composition	Each capsule contains;
	1	Tranexamic Acid500mg
	Diary No. Date of R & I & fee	Dy. No. 16376 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900221 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	B02AA02 Amino acids
	Type of Form	Form-5
	Finished product Specification	BP Specifications (couldn't be found in BP, available in JP)
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed in capsule dosage form
	Me-too status	Melaxic 500mg Capsule Reg. No. 113137 M/s Crystolite Pharmaceuticals.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	 Evidence of RRA approval of product in Capsule dosage form is required.
	 Decision: Deferred for following; Evidence of approval of applied form were adopted by the Registration Boa Section approval letter. Latest GMP inspection report/ certifities 	
421.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S3, National Industrial
		Zone, Rawat, Islamabad. (DML No.000551)
		Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tranex Injection 1g
	Composition	Each 5ml (ampoule) contains;
	1	Tranexamic Acid1g
	Diary No. Date of R & I & fee	Dy. No. 16383 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900232 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	B02AA02 Amino acids
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed in 1g/5ml Injection dosage form
	Me-too status	Transolide Injection 1g Reg. No. 068820 M/s Global Pharmaceuticals.
	GMP status	Certificate of 2018 is submitted.

	Remarks of the Evaluator	Evidence of RRA approval of formulation is required.
	Decision: Deferred for following;	
		<u> </u>
422.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S3, National Industrial
1224	Traine and address of management rippireant	Zone, Rawat, Islamabad. (DML No.000551)
	Down I Marrier Daniel Comment	Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tranex Injection 500mg
	Composition	Each 5ml (ampoule) contains; Tranexamic Acid500mg
	Diary No. Date of R & I & fee	Dy. No. 16381 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
	Diary No. Date of R & I & Ice	No. 1900229 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	B02AA02 Amino acids
	Type of Form	Form-5
	_ · ·	
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	TRANEXAMIC ACID 100 MG/ML SOLUTION FOR
	Regulatory Authorities	INJECTION
		MHRA Approved
	Me-too status	Transager Injection 500mg Reg. No. 110986
		M/s Allmed (Pvt.) Ltd.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	• Evidence of RRA approval of formulation is required.
	Decision: Deferred for following;	
	 Evidence of approval of applied form were adopted by the Registration Bos Section approval letter. 	nulation in reference regulatory authorities/agencies which ard in its 275 th meeting.
	Latest GMP inspection report/ certifity	icate.
423.		
		M/s. Ipram International, Plot No. 26, S.S3, National Industrial
		M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551)
		M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
	Brand Name + Dosage Form + Strength	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg
		M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains;
	Brand Name + Dosage Form + Strength Composition	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019.
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists Form-5
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists Form-5 USP Specifications As per SRO.
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists Form-5 USP Specifications
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists Form-5 USP Specifications As per SRO. FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral use
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists Form-5 USP Specifications As per SRO. FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral use USFDA Approved Soltim Capsule Reg. No. 111055
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists Form-5 USP Specifications As per SRO. FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral use USFDA Approved Soltim Capsule Reg. No. 111055 M/s Medisynth Pharma
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & 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	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists Form-5 USP Specifications As per SRO. FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral use USFDA Approved Soltim Capsule Reg. No. 111055 M/s Medisynth Pharma Certificate of 2018 is submitted.
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists Form-5 USP Specifications As per SRO. FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral use USFDA Approved Soltim Capsule Reg. No. 111055 M/s Medisynth Pharma Certificate of 2018 is submitted.
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & 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	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists Form-5 USP Specifications As per SRO. FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral use USFDA Approved Soltim Capsule Reg. No. 111055 M/s Medisynth Pharma Certificate of 2018 is submitted. • Section Approval is required. • Revised label claim as per RRAs along with fee of Rs.
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & 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	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists Form-5 USP Specifications As per SRO. FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral use USFDA Approved Soltim Capsule Reg. No. 111055 M/s Medisynth Pharma Certificate of 2018 is submitted.
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & 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: Deferred for following;	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists Form-5 USP Specifications As per SRO. FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral use USFDA Approved Soltim Capsule Reg. No. 111055 M/s Medisynth Pharma Certificate of 2018 is submitted. • Section Approval is required. • Revised label claim as per RRAs along with fee of Rs. 30000/- is required.
	Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & 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	M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Tamsin Capsule 0.4mg Each capsule contains; Tamsulosin Hydrochloride0.4mg Dy. No. 16386 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901899 dated 07-03-2019, endorsed on 07.03.2019. G04CA02 Alpha-adrenoreceptor antagonists Form-5 USP Specifications As per SRO. FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral use USFDA Approved Soltim Capsule Reg. No. 111055 M/s Medisynth Pharma Certificate of 2018 is submitted. • Section Approval is required. • Revised label claim as per RRAs along with fee of Rs. 30000/- is required.

	Latest GMP inspection report/ certification	icate.
424.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S3, National Industrial
		Zone, Rawat, Islamabad. (DML No.000551)
		Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tamsin-D Capsule 0.5mg/0.4mg
	Composition	Each capsule contains;
		Dutasteride0.5mg
		Tamsulosin Hydrochloride0.4mg
	Diary No. Date of R & I & fee	Dy. No. 16385 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
		No. 1900234 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	G04CA52 Alpha-adrenoreceptor antagonists
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	DUTASTERIDE/TAMSULOSIN 0.5/0.4 MG HARD
	Regulatory Authorities	CAPSULES
	76	MHRA Approved
	Me-too status	Maxflo-D Capsule Reg. No. 091571
	CMD	M/s CCL Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Section Approval is required.
		• Revised label claim as per RRAs along with fee of Rs.
		30000/- is required.
	Decision: Deferred for following;	
	Revision of label as per innovator pro	oduct.
	• Section approval letter.	
	Latest GMP inspection report/ certification	
425.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S3, National Industrial
		Zone, Rawat, Islamabad. (DML No.000551)
	D 1N D E (0) (1	Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tranex Injection 250mg
	Composition	Each 5ml (ampoule) contains;
	Diary No. Date of R & I & fee	Tranexamic Acid250mg Dy. No. 16380 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
	Diary No. Date of R & T & Ice	1 7
	•	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids
	Pharmacological Group Type of Form	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5
	Pharmacological Group Type of Form Finished product Specification	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO.
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534
	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	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534 Certificate of 2018 is submitted.
	Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534
	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	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534 Certificate of 2018 is submitted.
	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: Deferred for following;	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534 Certificate of 2018 is submitted. • Evidence of RRA approval of formulation is required.
	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: Deferred for following; • Evidence of approval of applied form	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534 Certificate of 2018 is submitted. • Evidence of RRA approval of formulation is required.
	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: Deferred for following; • Evidence of approval of applied form were adopted by the Registration Box	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534 Certificate of 2018 is submitted. • Evidence of RRA approval of formulation is required.
	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: Deferred for following; • Evidence of approval of applied form	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534 Certificate of 2018 is submitted. • Evidence of RRA approval of formulation is required.
	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: Deferred for following; • Evidence of approval of applied form were adopted by the Registration Bos • Section approval letter. • Latest GMP inspection report/ certification	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534 Certificate of 2018 is submitted. • Evidence of RRA approval of formulation is required. nulation in reference regulatory authorities/agencies which ard in its 275th meeting. icate.
426.	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: Deferred for following; • Evidence of approval of applied form were adopted by the Registration Bos • Section approval letter.	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534 Certificate of 2018 is submitted. • Evidence of RRA approval of formulation is required. nulation in reference regulatory authorities/agencies which ard in its 275th meeting. icate. M/s. Ipram International, Plot No. 26, S.S3, National Industrial
426.	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: Deferred for following; • Evidence of approval of applied form were adopted by the Registration Bos • Section approval letter. • Latest GMP inspection report/ certification	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534 Certificate of 2018 is submitted. • Evidence of RRA approval of formulation is required. nulation in reference regulatory authorities/agencies which ard in its 275th meeting. icate. M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551)
426.	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: Deferred for following; • Evidence of approval of applied form were adopted by the Registration Bos • Section approval letter. • Latest GMP inspection report/ certification and address of manufacturer/ Applicant	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534 Certificate of 2018 is submitted. • Evidence of RRA approval of formulation is required. nulation in reference regulatory authorities/agencies which ard in its 275th meeting. icate. M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.
426.	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: Deferred for following; • Evidence of approval of applied form were adopted by the Registration Bos • Section approval letter. • Latest GMP inspection report/ certification Name and address of manufacturer/ Applicant	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534 Certificate of 2018 is submitted. • Evidence of RRA approval of formulation is required. nulation in reference regulatory authorities/agencies which ard in its 275th meeting. icate. M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided. Ipralog-40 Injection
426.	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: Deferred for following; • Evidence of approval of applied form were adopted by the Registration Bos • Section approval letter. • Latest GMP inspection report/ certification and address of manufacturer/ Applicant	No. 1901900 dated 06-03-2019, endorsed on 06.03.2019. B02AA02 Amino acids Form-5 USP Specifications As per SRO. Could not be verified for strength of 250mg Transamin Injection 250mg Reg. No. 007534 Certificate of 2018 is submitted. • Evidence of RRA approval of formulation is required. nulation in reference regulatory authorities/agencies which ard in its 275th meeting. icate. M/s. Ipram International, Plot No. 26, S.S3, National Industrial Zone, Rawat, Islamabad. (DML No.000551) Section Approval not provided.

Diary No. Date of R & I & fee Dy. No. 16377 dated 07.03.2019. Fee paid Rs. 20.000/- vide Slip No. 1900222 dated 05.32-2019, endosed on 06.03.2019. Pharmacological Group H02AB08 CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN Type of Form Form-5 Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status Kentack doing Reg. No. 097783 M/s Rotes Pharma GMP status Certificate of 2018 is submitted. Remarks of the Evaluator Pecision: Deferred for following: Section approval letter. Latest GMP inspection report/ certificate. Latest GMP inspection report/ certificate. Name and address of manufacturer/ Applicant Composition Brand Name + Dosage Form + Strength No. 1900224 dated 05-32-2019, endorsed on 06.03.2019. Pharmacological Group No7AAS1 Anticholinesterases, combinations Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Reference Regulatory Authorities Reference Regulatory Authorities Reference Regulatory Brands Refere			
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Pharmacological Group J02AC02 Triazole and tetrazole derivatives		<u> </u>	
		Pharmacological Group	J02AC02 Triazole and tetrazole derivatives

	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Itraconazole 100mg Capsules, hard
	Regulatory Authorities	MHRA Approved.
	Me-too status	Sporanox Capsule Reg. No. 012647
		M/s Aspin Pharma (pvt.) Ltd. Karachi.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		Section Approval is required.
		• Revised label claim as per RRAs along with fee of Rs.
		30000/- is required.
	Decision: Deferred for following;	•
	Revision of label as per innovator pro	oduct.
	Section approval letter.	
	Latest GMP inspection report/ certifit	icate.
429.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S3, National Industrial
	Traine and address of manufactures, 12ppmant	Zone, Rawat, Islamabad. (DML No.000551)
		Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tradol Injection
	Composition	Each ampoule contains:
	Composition	Tramadol HCl50mg
	Diary No. Date of R & I & fee	Dy. No. 16378 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
	Blary 110. Bate of R & I & Ice	No. 1900223 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N02AX02 Other opioids
	Type of Form	Form-5
	Finished product Specification	In-house Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Provided reference is of 100mg Injection.
	Regulatory Authorities	Trovided reference is or rooming injection.
	Me-too status	Tamadol 50mg Injection Reg. No. 110692
		M/s Highnoon Laboratories
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		Section Approval is required.
		Evidence of RRA approval of formulation in 50ml packaging
		is required.
		Reference of finished product specifications is required.
	Decision: Deferred for following;	1 Reference of finished product specifications is required.
		nulation in reference regulatory authorities/agencies which
	were adopted by the Registration Box	
	• Section approval letter.	210 mooning
	Latest GMP inspection report/ certifit	icate
430.	Name and address of manufacturer/ Applicant	M/s. Ipram International, Plot No. 26, S.S3, National Industrial
100.	Traine and address of manaracture, rippireant	Zone, Rawat, Islamabad. (DML No.000551)
		Section Approval not provided.
	Brand Name + Dosage Form + Strength	Furmid Injection 20mg
	Composition	Each ampoule contains:
	Composition	Furosemide20mg
	Diary No. Date of R & I & fee	Dy. No. 16387 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
	Dialy 110. Date of K & I & Ice	No. 1900219 dated 07-03-2019, rece paid Rs. 20,000/- vide Ship No. 1900219 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	C03CA01 Sulfonamides, plain
	Type of Form	Form-5
	Finished product Specification	In-house Specifications (found in BP, USP & JP)
	Pack size & Demanded Price	As per SRO.
	1 den bize & Demanded I fice	110 per bitto.

	Approval status of product in Reference	Furosemide 20mg/2ml Solution for Injection.
	Regulatory Authorities Me-too status	MHRA Approved
	Me-too status	Lasix Injection 20mg Reg. No. 000230 M/s Sanofi-Aventis Pakistan Ltd. Karachi.
	CMD status	Certificate of 2018 is submitted.
	GMP status Remarks of the Evaluator	
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
		Section Approval is required. B. G. G. H. L.
		Reference of finished product specifications is required.
	Decision: Deferred for following;	
	Reference of finished product specifications are constant.	
	Latest GMP inspection report/ certifSection approval letter.	icate.
431.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	Losin Capsule 0.2mg
	Composition	Each capsule contains:
	•	Tamsulosin HCl (as sustained release pellets)0.2mg
	Diary No. Date of R & I & fee	Dy. No. 13497 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
		No. 0833287 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	G04CA02 Alpha-adrenoreceptor antagonists
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	PMDA Approved
	Me-too status	Xhyva SR Capsule 0.2mg Reg. No. 110142
		M/s MKB Pharma.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		Source of pellets is required.
	Decision: Deferred for following;	1
	 Source of pellets. 	
	Latest GMP inspection report/ certifity	
432.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
		Section Approval not provided.
	Brand Name + Dosage Form + Strength	Losin Suspension 0.4mg
	Composition	Each 5ml contains:
	D' N D CD O Y C	Tamsulosin HCl0.4mg
	Diary No. Date of R & I & fee	Dy. No. 13499 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0833289 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	G04CA02 Alpha-adrenoreceptor antagonists
	Type of Form	Form-5
	Finished product Specification	In-house Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Not Found
	Me-too status	Not Found
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		Section Approval is required.
		Evidence of RRA approval of formulation is required.
		Evidence of availability of Me-too is required.
	Decision: Deferred for following:	
	• Evidence of applied formulation/drug al registration number, brand name and na	ready approved by DRAP (generic / me-too status) alongwith ame of firm.

	 Evidence of approval of applied formula declared/approved by the Registration B Latest GMP inspection report/ certificate Section approval letter. 	
433.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	Glipx Tablet 2.5mg
	Composition	Each film-coated tablet contains:
		Saxagliptin as HCl2.5mg
	Diary No. Date of R & I & fee	Dy. No. 13486 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844121 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A10BH03 Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Finished product Specification	In-house Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Onglyza 2.5 mg film-coated tablets
	Regulatory Authorities	MHRA Approved
	Me-too status	Saglip 2.5mg Tablet Reg. No. 071487.
		Mfg. by M/s CCL Lahore.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Decision: Deferred for following; • Latest GMP inspection report/ certif • Clarification of salt form of the drug	icate. substance with reference to the innovator product.
434.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
	**	National Industrial Zone, Rawat, Islamabad. (DML No.000613)
		Section Approval not provided.
	Brand Name + Dosage Form + Strength	Glipx Tablet 5mg
	Composition	Each film-coated tablet contains:
		Saxagliptin as HCl5mg
	Diary No. Date of R & I & fee	Dy. No. 13485 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
		No. 0844120 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A 10PH03 Diportidy Lantidese 4 (DDD 4) inhibitors
1	Pharmacological Group	A10BH03 Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Type of Form	Form-5
	Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference	Form-5 In-house Specifications As per SRO. SAXAGLIPTIN SANDOZ 5 MG FILM-COATED TABLETS
	Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	Form-5 In-house Specifications As per SRO. SAXAGLIPTIN SANDOZ 5 MG FILM-COATED TABLETS MHRA Approved
	Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference	Form-5 In-house Specifications As per SRO. SAXAGLIPTIN SANDOZ 5 MG FILM-COATED TABLETS
	Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	Form-5 In-house Specifications As per SRO. SAXAGLIPTIN SANDOZ 5 MG FILM-COATED TABLETS MHRA Approved Saglip 5mg Tablet Reg. No. 071486.
	Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status	Form-5 In-house Specifications As per SRO. SAXAGLIPTIN SANDOZ 5 MG FILM-COATED TABLETS MHRA Approved Saglip 5mg Tablet Reg. No. 071486. Mfg. by M/s CCL Lahore.
	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: Deferred for following; • Latest GMP inspection report/ certifications	In-house Specifications As per SRO. SAXAGLIPTIN SANDOZ 5 MG FILM-COATED TABLETS MHRA Approved Saglip 5mg Tablet Reg. No. 071486. Mfg. by M/s CCL Lahore. Certificate of 2018 is submitted. Latest GMP inspection report/ certificate is required.
435.	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: Deferred for following; • Latest GMP inspection report/ certif • Clarification of salt form of the drug Name and address of manufacturer/ Applicant	In-house Specifications As per SRO. SAXAGLIPTIN SANDOZ 5 MG FILM-COATED TABLETS MHRA Approved Saglip 5mg Tablet Reg. No. 071486. Mfg. by M/s CCL Lahore. Certificate of 2018 is submitted. Latest GMP inspection report/ certificate is required. icate. substance with reference to the innovator product. M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Section Approval not provided.
435.	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: Deferred for following; • Latest GMP inspection report/ certified Clarification of salt form of the drug	In-house Specifications As per SRO. SAXAGLIPTIN SANDOZ 5 MG FILM-COATED TABLETS MHRA Approved Saglip 5mg Tablet Reg. No. 071486. Mfg. by M/s CCL Lahore. Certificate of 2018 is submitted. • Latest GMP inspection report/ certificate is required. icate. substance with reference to the innovator product. M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Section Approval not provided. Colicit Tablet 500mg
435.	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: Deferred for following; • Latest GMP inspection report/ certif • Clarification of salt form of the drug Name and address of manufacturer/ Applicant	In-house Specifications As per SRO. SAXAGLIPTIN SANDOZ 5 MG FILM-COATED TABLETS MHRA Approved Saglip 5mg Tablet Reg. No. 071486. Mfg. by M/s CCL Lahore. Certificate of 2018 is submitted. • Latest GMP inspection report/ certificate is required. icate. substance with reference to the innovator product. M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Section Approval not provided. Colicit Tablet 500mg Each film-coated tablet contains:
435.	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: Deferred for following; • Latest GMP inspection report/ certif • Clarification of salt form of the drug Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	In-house Specifications As per SRO. SAXAGLIPTIN SANDOZ 5 MG FILM-COATED TABLETS MHRA Approved Saglip 5mg Tablet Reg. No. 071486. Mfg. by M/s CCL Lahore. Certificate of 2018 is submitted. • Latest GMP inspection report/ certificate is required. icate. substance with reference to the innovator product. M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Section Approval not provided. Colicit Tablet 500mg Each film-coated tablet contains: Citicoline as Sodium500mg
435.	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: Deferred for following; • Latest GMP inspection report/ certif • Clarification of salt form of the drug Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	In-house Specifications As per SRO. SAXAGLIPTIN SANDOZ 5 MG FILM-COATED TABLETS MHRA Approved Saglip 5mg Tablet Reg. No. 071486. Mfg. by M/s CCL Lahore. Certificate of 2018 is submitted. • Latest GMP inspection report/ certificate is required. icate. substance with reference to the innovator product. M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Section Approval not provided. Colicit Tablet 500mg Each film-coated tablet contains:

	Type of Form	Form-5
l —	Finished product Specification	In-house Specifications
	Pack size & Demanded Price	As per SRO.
 	Approval status of product in Reference	Not Found
1	Regulatory Authorities	Not I ound
I —	Me-too status	Not Found
 	GMP status	Certificate of 2018 is submitted.
I —	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Remarks of the Evaluator	 Section Approval is required.
		• Evidence of RRA approval of formulation is required.
	D	• Evidence of availability of Me-too in film-coating is required.
	Decision: Deferred for following:	
	 Evidence of applied formulation/drug all registration number, brand name and na 	ready approved by DRAP (generic / me-too status) alongwith
		ation in reference regulatory authorities/agencies which were
	 Evidence of approval of applied formula declared/approved by the Registration Bo 	
	• Latest GMP inspection report conducted Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
430.	Name and address of manufacturer/ Applicant	National Industrial Zone, Rawat, Islamabad. (DML No.000613)
_	Drand Name Dassage Form Strongth	Section Approval not provided.
	Brand Name + Dosage Form + Strength	Colicit Syrup 500mg/5ml Each 5ml contains:
	Composition	
	Diam. No. Data of D. C. I. C. for	Citicoline as Sodium500mg
	Diary No. Date of R & I & fee	Dy. No. 13496 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844050 dated 06-03-2019, endorsed on 06.03.2019.
_	Pharmacological Group	N0. 0844030 dated 06-03-2019, endotsed on 06.05.2019. N06BX06 Other psychostimulants and nootropics
	Pharmacological Group Type of Form	Form-5
I —	Finished product Specification	In-house Specifications
	Pack size & Demanded Price	As per SRO.
l <u>-</u>		SOMAZINE 100 mg/ml Oral Solution CIMA Spain Approved
	Approval status of product in Reference Regulatory Authorities	SOMAZINE 100 mg/mi Orai Solution Chira Spain Approved
I —	Me-too status	Citicode Syrup by Rotex Pharma
	GMP status	Certificate of 2018 is submitted.
 	Remarks of the Evaluator	
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required. Section Approval is required.
_		Section Approval is required.
	Decision: Deferred for following:	
	• Latest GMP inspection report conducted	within last three years.
	• Section approval letter.	
437.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
	D 11 D D 0 1	National Industrial Zone, Rawat, Islamabad. (DML No.000613)
I	Brand Name + Dosage Form + Strength	Tin Tablet 1mg
	Composition	Each Film-coated tablet contains:
		Pitavastatin as Calcium1mg
	Diary No. Date of R & I & fee	Dy. No. 13478 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
		No. 0844006 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	C10AA08 HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	In-house Specifications (found in JP)
 	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	ALIPZA 1MG FILM-COATED TABLETS
I —	Regulatory Authorities	MHRA Approved
 	Me-too status	Pinstatin 1mg Reg. No. 107112 by Moringa Pharma
I —	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
1		 Reference of finished product specifications is required.

	within last three years along with fee of	Firm shall submit latest GMP inspection report conducted Rs. 7,500/- for correction/pre-approval change in product 11/2012-B&A/DRAP dated 07-05-2021 before issuance of
438.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
430.	Tvaine and address of manufacture/ Applicant	National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	D 1M . D E . C. 4	
	Brand Name + Dosage Form + Strength	Tin Tablet 2mg
	Composition	Each Film-coated tablet contains:
		Pitavastatin as Calcium2mg
	Diary No. Date of R & I & fee	Dy. No. 13479 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
		No. 0844007 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	C10AA08 HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	In-house Specifications (found in JP)
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	ALIPZA 2MG FILM-COATED TABLETS
	Regulatory Authorities	MHRA Approved
	Me-too status	Pinstatin 2mg Reg. No. 107113 by Moringa Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
		Section Approval is required.
		• Reference of finished product specifications is required.
	within last three years along with fee of	Firm shall submit latest GMP inspection report conducted Rs. 7,500/- for correction/pre-approval change in product 11/2012-B&A/DRAP dated 07-05-2021 before issuance of
439.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	Tin Tablet 4mg
	Composition	Each Film-coated tablet contains:
	Composition	Pitavastatin as Calcium4mg
	Diary No. Date of R & I & fee	Dy. No. 13480 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
		No. 0844008 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	C10AA08 HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	In-house Specifications (found in JP)
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	ALIPZA 4MG FILM-COATED TABLETS
	Regulatory Authorities	MHRA Approved
	Me-too status	Pinstatin 4mg Reg. No. 107114 by Moringa Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		Section Approval is required.
		Reference of finished product specifications is required.
	within last three years along with fee of	Firm shall submit latest GMP inspection report conducted Rs. 7,500/- for correction/pre-approval change in product 11/2012-B&A/DRAP dated 07-05-2021 before issuance of
440.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	Ronol Tablet 80mg
	Composition	Each Film-coated tablet contains:
	Composition	Hydrated Phloroglucinol80mg corresponding to anhydrous
	Diam No Data of D 0 1 0 ft	Phloroglucinol62.233mg
	Diary No. Date of R & I & fee	Dy. No. 16440 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0833290 dated 07-03-2019, endorsed on 07.03.2019.

	Pharmacological Group	A03AX12 Other drugs for functional gastrointestinal disorders
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Not Found
	Regulatory Authorities	Not I ound
	Me-too status	Not found
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required. DRA
		Evidence of RRA approval of formulation is required.
		Evidence of availability of Me-too is required.
	Decision: Deferred for following:	
		ready approved by DRAP (generic / me-too status) alongwith
	registration number, brand name and na	
		ation in reference regulatory authorities/agencies which were
	declared/approved by the Registration B	
444	Latest GMP inspection report/ certificate	
441.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
		National Industrial Zone, Rawat, Islamabad. (DML No.000613)
		Section Approval not provided.
	Brand Name + Dosage Form + Strength	Ronol Suspension 80mg
	Composition	Each 5ml contains:
	D' N D (CD 0 1 0 C	Hydrated Phloroglucinol80mg
	Diary No. Date of R & I & fee	Dy. No. 16441 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
	N 1 1 1 C	No. 0833291 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	A03AX12 Other drugs for functional gastrointestinal disorders
	Type of Form	Form-5
	Finished product Specification	In-house GP C
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Not Found
	Regulatory Authorities Me-too status	N-4 C 1
	GMP status	Not found Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required. Company of the c
		Evidence of RRA approval of formulation is required.
		Evidence of availability of Me-too is required.
	Decision: Deferred for following:	
		ready approved by DRAP (generic / me-too status) alongwith
	registration number, brand name and na	
		ation in reference regulatory authorities/agencies which were
	declared/approved by the Registration B	
	Latest GMP inspection report/certificate	
442.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
		National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	Get Tablet 8mg
	Composition	Each Film-coated tablet contains:
		Ondansetron Hydrochloride Dihydrate eq. to
	D' N D (CD 0 1 0 C	Ondansetron8mg
	Diary No. Date of R & I & fee	Dy. No. 13484 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
	Diameter 1 Comme	No. 0844119 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A04AA01 Serotonin (5HT3) antagonists
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Ondansetron 8 mg (Ondansetron Hydrochloride dihydrate)
1	Regulatory Authorities	MHRA Approved.

1	Me-too status	Zofran Tablets 8 mg Reg. No. 020668
	Wie-too status	M/s GSK Karachi.
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	
	Decision: Approved. Firm shall submit latest before issuance of registration letter.	GMP inspection report conducted within last three years along
443.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
		National Industrial Zone, Rawat, Islamabad. (DML No.000613)
	Brand Name + Dosage Form + Strength	PIO-G Tablet 30mg/2mg
	Composition	Each tablet contains:
		Pioglitazone as HCl30mg
		Glimepiride2mg
	Diary No. Date of R & I & fee	Dy. No. 13481 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
	N 1 1 C	No. 0844009 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A10BD06 Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5
	Finished product Specification Pack size & Demanded Price	USP Specifications As per SRO.
		Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30
	Approval status of product in Reference Regulatory Authorities	mg/2 mg uncoated tablet)
	Regulatory Authorities	FDA Approved
	Me-too status	Piozer-G 30/2 Tablets Reg. No. 050690
	Wie-too status	M/s Hilton Pharma (Pvt) Ltd., 13, Sector-15, Korangi
		Industrial Area, Karachi
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		1 1
		GMP inspection report conducted within last three years along
444.	before issuance of registration letter.	
444.		GMP inspection report conducted within last three years along M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613)
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HC130mg Glimepiride4mg
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HC130mg
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HC130mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019.
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HC130mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HC130mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HC130mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5 USP Specifications
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HC130mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5 USP Specifications As per SRO.
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HCl30mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5 USP Specifications As per SRO. Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HC130mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5 USP Specifications As per SRO. Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/4 mg uncoated tablet)
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HCl30mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5 USP Specifications As per SRO. Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/4 mg uncoated tablet) FDA Approved
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HCl30mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5 USP Specifications As per SRO. Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/4 mg uncoated tablet) FDA Approved Piozer-G 30/4 Tablets Reg. No. 050691
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HCl30mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5 USP Specifications As per SRO. Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/4 mg uncoated tablet) FDA Approved Piozer-G 30/4 Tablets Reg. No. 050691 M/s Hilton Pharma (Pvt) Ltd., 13, Sector-15, Korangi
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities Me-too status	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HCl30mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5 USP Specifications As per SRO. Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/4 mg uncoated tablet) FDA Approved Piozer-G 30/4 Tablets Reg. No. 050691 M/s Hilton Pharma (Pvt) Ltd., 13, Sector-15, Korangi Industrial Area, Karachi
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HCl30mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5 USP Specifications As per SRO. Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/4 mg uncoated tablet) FDA Approved Piozer-G 30/4 Tablets Reg. No. 050691 M/s Hilton Pharma (Pvt) Ltd., 13, Sector-15, Korangi
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & 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	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HCl30mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5 USP Specifications As per SRO. Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/4 mg uncoated tablet) FDA Approved Piozer-G 30/4 Tablets Reg. No. 050691 M/s Hilton Pharma (Pvt) Ltd., 13, Sector-15, Korangi Industrial Area, Karachi Certificate of 2018 is submitted. • Latest GMP inspection report/ certificate is required.
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & 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	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HCl30mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5 USP Specifications As per SRO. Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/4 mg uncoated tablet) FDA Approved Piozer-G 30/4 Tablets Reg. No. 050691 M/s Hilton Pharma (Pvt) Ltd., 13, Sector-15, Korangi Industrial Area, Karachi Certificate of 2018 is submitted.
444.	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & 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. Firm shall submit latest	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HCl30mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5 USP Specifications As per SRO. Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/4 mg uncoated tablet) FDA Approved Piozer-G 30/4 Tablets Reg. No. 050691 M/s Hilton Pharma (Pvt) Ltd., 13, Sector-15, Korangi Industrial Area, Karachi Certificate of 2018 is submitted. • Latest GMP inspection report/ certificate is required.
	before issuance of registration letter. Name and address of manufacturer/ Applicant Brand Name + Dosage Form + Strength Composition Diary No. Date of R & I & 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. Firm shall submit latest before issuance of registration letter.	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) PIO-G Tablet 30mg/4mg Each tablet contains: Pioglitazone as HCl30mg Glimepiride4mg Dy. No. 13482 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844010 dated 06-03-2019, endorsed on 06.03.2019. A10BD06 Combinations of oral blood glucose lowering drugs Form-5 USP Specifications As per SRO. Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/4 mg uncoated tablet) FDA Approved Piozer-G 30/4 Tablets Reg. No. 050691 M/s Hilton Pharma (Pvt) Ltd., 13, Sector-15, Korangi Industrial Area, Karachi Certificate of 2018 is submitted. • Latest GMP inspection report/ certificate is required. GMP inspection report conducted within last three years along

	Composition	Each film-coated tablet contains:
		Linagliptin5mg
	Diary No. Date of R & I & fee	Dy. No. 13487 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip
		No. 0844122 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A10BH05 Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Finished product Specification	In-house Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	
	Regulatory Authorities	MHRA Approved
	Me-too status	Encylin 5mg Tablets Reg. No. 110863
		M/s Jenner Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		Section Approval is required.
	Decision: Approved with Innovator's Spec	ifications. Firm shall submit latest GMP inspection report
		Gee of Rs. 7,500/- for correction/pre-approval change in product 11/2012-B&A/DRAP dated 07-05-2021, before issuance of
	registration letter.	
446.	Name and address of manufacturer/	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
	Applicant	National Industrial Zone, Rawat, Islamabad. (DML
		No.000613)
		Capsule Section (general)
	Brand Name + Dosage Form +	Gaybal Capsule 150mg
	Strength	5
	Composition	Each capsule contains:
		Pregabalin150mg
	Diary No. Date of R & I & fee	Dy. No. 13477 dated 07.03.2019. Fee paid Rs. 20,000/- vide
		Slip No. 0844005 dated 06-03-2019, endorsed on
		06.03.2019.
	Pharmacological Group	N02BF02 Gabapentinoids
	Type of Form	Form-5
	Finished product Specification	In-house Specifications (found in BP)
	1 1	
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	Pregabalin Noumed 25, 50, 75, 100, 150, 200, 225 and
	Regulatory Authorities	300mg Capsules, hard (pregabalin) - PL 44041/0065-
		0072
		MHRA Approved.
	Me-too status	Gabica 150 mg Capsule Reg. No. 048724
		M/s Getz Pharma (Pvt) Ltd Karachi
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Decision: Approved with BP Specifica	tions.
		report conducted within last three years along with fee of Rs.
		e in product specifications as per notification No.F.7-11/2012-
	B&A/DRAP dated 07-05-2021, before issu	
447.	Name and address of manufacturer/	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
	Applicant	National Industrial Zone, Rawat, Islamabad. (DML
		No.000613)
		Oral dry powder suspension (general)
	Brand Name + Dosage Form +	Clear Suspension 5mg/5ml
	Strength	Crown Suspension Sing/Sim
	Suchgui	

	G :::	T 1 5 1 6 (1)
	Composition	Each 5ml after reconstitution contains:
	Diamy No. Data of D. & I. & foo	Montelukast as Sodium5mg Dy. No. 13498 dated 07.03.2019. Fee paid Rs. 20,000/- vide
	Diary No. Date of R & I & fee	Slip No. 0833288 dated 06-03-2019, endorsed on
		06.03.2019.
	Pharmacalagical Group	
	Pharmacological Group	R03DC03 Leukotriene receptor antagonists
	Type of Form	Form-5
	Finished product Specification	In-house Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Provided reference is of sachet
	Me-too status	Synkast Dry Suspension Reg. No. 076929
		M/s Synchro Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		Evidence of RRA approval of formulation in bottle
		packing is required.
	Decision: Deferred for following:	paening is required.
	• Evidence of approval of applied f	formulation in reference regulatory authorities/agencies
	which were declared/approved by	the Registration Board in its 275th meeting.
	• Latest GMP inspection report/ cer	tificate conducted within last three years.
448.	Name and address of manufacturer/	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
	Applicant	National Industrial Zone, Rawat, Islamabad. (DML
		No.000613)
		Capsule (general) Section.
	Brand Name + Dosage Form +	Cis Capsule 375mg
	Strength	
	Composition	Each hard gelatin capsule contains:
		Carbocisteine375mg
	Diary No. Date of R & I & fee	Dy. No. 13490 dated 07.03.2019. Fee paid Rs. 20,000/- vide
		Slip No. 0844125 dated 06-03-2019, endorsed on
		06.03.2019.
	Pharmacological Group	R05CB03 Mucolytics
	Type of Form	Form-5
	Finished product Specification	In-house Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	CARBOCISTEINE 375MG CAPSULES
	Regulatory Authorities	MHRA Approved
	Me-too status	Carbex Capsule Reg. No. 075962
		M/s Platinum Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Decision: Approved with Innovator's	
		report conducted within last three years along with fee of Rs.
		e in product specifications as per notification No.F.7-11/2012-
449.	B&A/DRAP dated 07-05-2021, before issu Name and address of manufacturer/	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
447.		
	Applicant	National Industrial Zone, Rawat, Islamabad. (DML No.000613)
		Capsule (general) Section.
		Capsure (general) section.

	Brand Name + Dosage Form + Strength	CETA Capsule 400mg
	Composition	Each hard gelatin capsule contains:
	Diary No. Date of R & I & fee	Piracetam400mg Dy. No. 13491 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844126 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N06BX03 Other psychostimulants and nootropics
	Type of Form	Form-5
	Finished product Specification	In-house Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed
	Me-too status	Ucetam Capsule Reg. No. 021955 M/s Al-Habib Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		approval of applied formulation in reference regulatory by the Registration Board in its 275 th meeting.
450.	Name and address of manufacturer/	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
	Applicant	National Industrial Zone, Rawat, Islamabad. (DML
		No.000613)
	Dura I Name at Dance France	Oral liquid general section.
	Brand Name + Dosage Form + Strength	Levecetam Oral Solution 100mg/ml
	Composition	Each ml contains:
	_	Levetiracetam100mg
	Diary No. Date of R & I & fee	Dy. No. 13493 dated 07.03.2019. Fee paid Rs. 20,000/- vide
		Slip No. 0844047 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N03AX14 Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	In-house Specifications (found in USP)
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	LEVETIRACETAM CRESCENT 100 MG/ML ORAL SOLUTION
	Me-too status	MHRA Approved Lecetam Oral Solution Reg. No. 112608 M/s Indus Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	7,500/- for correction/pre-approval chang	report conducted within last three years along with fee of Rs. e in product specifications as per notification No.F.7-11/2012-
451.	Name and address of manufacturer/	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
431.	Applicant	National Industrial Zone, Rawat, Islamabad. (DML No.000613)
		Capsule (general) Section.
<u> </u>		Cuponic (Scholar) Section.

	Brand Name + Dosage Form +	Cool Capsule 4mg
	Strength	
	Composition	Each hard gelatin capsule contains: Thiocolchicoside4mg
	Diary No. Date of R & I & fee	Dy. No. 13492 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844127 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M03BX05 Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	In-house Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MIOREL 4 mg, capsule ANSM France Approved
	Me-too status	Thiolax Capsule by S.J&G Fazul Ellahie
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
1.50	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu	report conducted within last three years along with fee of Rs. e in product specifications as per notification No.F.7-11/2012-pance of registration letter.
452.	Name and address of manufacturer/	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05,
	Applicant	National Industrial Zone, Rawat, Islamabad. (DML
		No.000613)
		Tablet general Section.
	Brand Name + Dosage Form + Strength	T-SART Plus Tablet 80mg/12.5mg
	Composition	Each tablet contains:
		Telmisartan80mg
		Hydrochlorothiazide12.5mg
	Diary No. Date of R & I & fee	Dy. No. 13483 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844118 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	C09DA07 Angiotensin II receptor blockers (ARBs) and diuretics
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	TELMISARTAN AND HYDROCHLOROTHIAZIDE CRESENT 80MG/12.5MG TABLETS MHRA Approved
	Me-too status	Elsart-H Reg. No. 112705 M/s High-Q Pharma
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Decision: Approved. Registration lette certificate/inspection report.	er shall be issued after submission of latest GMP
453.	Name and address of manufacturer/ Applicant	M/s. Goodman Laboratories (Pvt.) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. (DML No.000613) Capsule (general) Section.

	Brand Name + Dosage Form + Strength	ERD Capsule 150mg
	Composition	Each hard gelatin capsule contains: Erdosteine150mg
	Diary No. Date of R & I & fee	Dy. No. 13495 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844049 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	R05CB15 Mucolytics
	Type of Form	Form-5
	Finished product Specification	Inhouse Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	ERDOTIN 150 MG CAPSULE RIGIDE. AIFA approved
	Me-too status	Dostin Capsules 150mg. Reg. No. 032332
	GMP status	Certificate of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	7,500/- for correction/pre-approval chang B&A/DRAP dated 07-05-2021, before issu	report conducted within last three years along with fee of Rs. e in product specifications as per notification No.F.7-11/2012- nance of registration letter.
454.	Name and address of manufacturer/	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6,
	Applicant	National Industrial Zone, Rawat, Islamabad (DML
		No.000600)
		Topical (steroid) Section.
	Brand Name + Dosage Form + Strength	Dermasol Cream 0.05%
	Composition	Each gram contains:
		Clobetasol Propionate0.5mg
	Diary No. Date of R & I & fee	Dy. No. 13692 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901274 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	D07AD01 Corticosteroids, very potent (group IV)
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Clobetasol Propionate 0.05% w/w Ointment (PL17507/00236) MHRA Approved.
	Me-too status	Clobetol ointment 0.05% Reg. No. 065177 M/s Valor Pharmaceuticals Islamabad
	GMP status	report of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit years before issuance of registration letter	latest GMP inspection report conducted within last three r.
455.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Capsule(general) section.
	Brand Name + Dosage Form + Strength	Cymol Capsule 30mg

	Composition	Each hard gelatin capsule contains:
	Composition	Duloxetine Hydrochloride (as Enteric Coated Pellets) eq. to
		Duloxetine30mg
	Diary No. Date of R & I & fee	Dy. No. 13683 dated 07.03.2019. Fee paid Rs. 20,000/- vide
	Blary 100. Bate of It & T & Ice	Slip No. 1901264 dated 07-03-2019, endorsed on
		07.03.2019.
	Pharmacological Group	N06AX21 Other antidepressants
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	MHRA Approved
	Regulatory Authorities	
	Me-too status	Dulan Capsule by Hilton
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
		Source of Pellets is required.
	Decision: Approved. Firm shall submit	latest GMP inspection report conducted within last three years
		long with of documents for source of pellets along with
	requisite fee (in case of imported sour	
456.	Name and address of manufacturer/	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6,
	Applicant	National Industrial Zone, Rawat, Islamabad (DML
		No.000600)
		Tablet (general) Section.
	Brand Name + Dosage Form +	Paroxilex CR Tablet 12.5mg
	Strength	
	Composition	Each extended release tablet contains:
		Paroxetine as Hydrochloride12.5mg
	Diary No. Date of R & I & fee	Dy. No. 13798 dated 07.03.2019. Fee paid Rs. 20,000/- vide
		Slip No. 0817898 dated 07-03-2019, endorsed on
	DI 1 1 G	07.03.2019.
	Pharmacological Group	N06AB05 Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	PAXIL CR, Paroxetine hydrochloride (eq to base: 12.5mg,
	Regulatory Authorities	25mg, 37.5mg) tablet extended release.
		USFDA Approved.
	Me-too status	Seroxat CR tablet 12.5mg Reg. No. 043058
		M/s GSK Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Decision: Approved Firm shall submit	latest GMP inspection report conducted within last three
	years before issuance of registration letter	r.
457.	Name and address of manufacturer/	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6,
	Applicant	National Industrial Zone, Rawat, Islamabad (DML
		No.000600)
		Tablet (general) Section
	Brand Name + Dosage Form +	Paroxilex CR Tablet 25mg
	Strength Composition	Each extended release tablet contains:
	Composition	
		Paroxetine as Hydrochloride25mg

	Diary No. Date of R & I & fee	Dy. No. 13799 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0817899 dated 07-03-2019, endorsed on
		07.03.2019.
	Pharmacological Group	N06AB05 Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
		*
	Approval status of product in Reference	PAXIL CR, Paroxetine hydrochloride (eq to base: 12.5mg,
	Regulatory Authorities	25mg, 37.5mg) tablet extended release.
	26	USFDA Approved.
	Me-too status	Seroxat CR tablet 25mg Reg. No. 043059
	CDE	M/s GSK Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit years before issuance of registration letter	latest GMP inspection report conducted within last three r.
458.	Name and address of manufacturer/	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6,
	Applicant	National Industrial Zone, Rawat, Islamabad (DML
		No.000600)
		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Paroxilex CR Tablet 37.5mg
	Composition	Each extended release tablet contains:
		Paroxetine as Hydrochloride37.5mg
	Diary No. Date of R & I & fee	Dy. No. 13800 dated 07.03.2019. Fee paid Rs. 20,000/- vide
		Slip No. 0817900 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N06AB05 Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference	PAXIL CR, Paroxetine hydrochloride (eq to base: 12.5mg,
	Regulatory Authorities	25mg, 37.5mg) tablet extended release.
	Trogulatory Traditorities	USFDA Approved.
	Me-too status	Xtin CR tablet 37.5mg Reg. No. 112923
	THE too status	M/s Siam Pharma.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	 Latest GMP inspection report/ certificate is required.
	Decision: Approved Firm shall submit	latest GMP inspection report conducted within last three years
459.	before issuance of registration letter. Name and address of manufacturer/	
439.		M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6,
	Applicant	National Industrial Zone, Rawat, Islamabad (DML
		No.000600)
	D 111 D E	Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Lacosa Tablet 100mg
	Composition	Each film-coated tablet contains:
	D' N D C C C C C	Lacosamide100mg
	Diary No. Date of R & I & fee	Dy. No. 13689 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901271 dated 07-03-2019, endorsed on

	07.03.2019.			
	Pharmacological Group	N03AX18 Other antiepileptics		
	Type of Form	Form-5		
	Finished product Specification	As per Innovator (found in BP, USP)		
	Pack size & Demanded Price	As per SRO.		
	Approval status of product in Reference	MHRA Approved		
	Regulatory Authorities			
	Me-too status	Lacolep tablet by Hilton		
	GMP status	Report of 2018 is submitted.		
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.		
	Decision: Approved with USP Specifications. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter and fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.			
460.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Tablet (general) Section.		
	Brand Name + Dosage Form + Strength	Lacosa Tablet 150mg		
	Composition	Each film-coated tablet contains: Lacosamide150mg		
	Diary No. Date of R & I & fee	Dy. No. 13690 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901272 dated 07-03-2019, endorsed on 07.03.2019.		
	Pharmacological Group	N03AX18 Other antiepileptics		
	Type of Form	Form-5		
	Finished product Specification	As per Innovator (found in BP, USP)		
	Pack size & Demanded Price	As per SRO.		
	Approval status of product in Reference Regulatory Authorities	MHRA Approved		
	Me-too status	Lacolep tablet by Hilton		
	GMP status	Report of 2018 is submitted.		
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.		
	Decision: Approved with USP Specifications. Registration letter shall be issued after submission of latest GMP certificate/inspection report and fee of Rs. 7500/- as per SRO496(I)/2023 dated 17.04.2023.			
461.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Tablet (general) section.		
	Brand Name + Dosage Form + Strength	Doxofin Tablet 400mg		
	Composition	Each tablet contains: Doxofylline400mg		
	Diary No. Date of R & I & fee	Dy. No. 13700 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901283 dated 07-03-2019, endorsed on 07.03.2019.		
	Pharmacological Group	R03DA11 Xanthines		
	Type of Form	Form-5		

	Finished product Specification	As per Innovator	
	Pack size & Demanded Price	As per SRO.	
	Approval status of product in Reference	AIFA Italy Approved	
	Regulatory Authorities		
	Me-too status	Xofi Tablet by Hilton	
	GMP status	Report of 2018 is submitted.	
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.	
	Decision: Approved. Registration lette certificate/inspection report.	r shall be issued after submission of latest GMP	
462.	Name and address of manufacturer/	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6,	
	Applicant	National Industrial Zone, Rawat, Islamabad (DML	
		No.000600)	
		Tablet (general) Section.	
	Brand Name + Dosage Form + Strength	Pain-Go Tablet 4mg	
	Composition	Each film-coated tablet contains:	
		Lornoxicam4mg	
	Diary No. Date of R & I & fee	Dy. No. 13684 dated 07.03.2019. Fee paid Rs. 20,000/- vide	
		Slip No. 1901265 dated 07-03-2019, endorsed on	
		07.03.2019.	
	Pharmacological Group	M01AC05 Oxicams	
	Type of Form	Form-5	
	Finished product Specification	In-house Specifications	
	Pack size & Demanded Price	As per SRO.	
	Approval status of product in Reference Regulatory Authorities	Xefo 4mg film-coated tablet (EMA approved)	
	Me-too status	Xonica 4mg Tablet by M/s Zephyr Pharmatec (Reg#086984)	
	GMP status	Report of 2018 is submitted.	
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.	
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/inspection report.		
463.	Name and address of manufacturer/	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6,	
	Applicant	National Industrial Zone, Rawat, Islamabad (DML No.000600)	
		Tablet (general) Section.	
	Brand Name + Dosage Form + Strength	Ariper Tablet 10mg	
	Composition	Each tablet contains:	
	Composition	Aripiprazole15mg	
	Diary No. Date of R & I & fee	Dy. No. 13805 dated 07.03.2019. Fee paid Rs. 20,000/- vide	
	Binary Tvo. Bine of It & T& T&	Slip No. 1900298 dated 07-03-2019, endorsed on 07.03.2019.	
	Pharmacological Group	N05AX12 Other antipsychotics	
	Type of Form	Form-5	
	Finished product Specification	USP Specifications	
	Pack size & Demanded Price	As per SRO.	
	Approval status of product in Reference	Aripiprazole 5, 10, 15 and 30 mg tablets (aripiprazole) - PL	
	Regulatory Authorities	24837/0050-0053; UK/H/5676/001-004/DC	
		MHRA Approved.	

Me-too status	Mactril tablet 15mg Reg. No. 067735 M/s Wilshire Laboratories Lahore.	
GMP status	Report of 2018 is submitted.	
Remarks of the Evaluator	 Latest GMP inspection report/ certificate is required. Correction of strength is required along with fee of Rs. 30000/- as brand name indicates 10mg while composition indicates 15mg strength. 	
Decision: Deferred for following;		
Latest GMP inspection report cor	nducted within last three years.	
 Clarification of applied strengt 	gth and label.	

Differential fee cases

464.	Name and address of manufacturer/ Applicant	M/s Pacific Pharmaceuticals Ltd. 30KM Multan Road, Lahore (DML No. 000295) Topical cream/ ointment/ Gel (general) Section.		
	Brand Name + Dosage Form + Strength	Ismagel 0.05% Gel		
	Composition	Each 100gm contains; Isotretinoin50mg		
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 4778 dated 27.4.2011 R&I verified.		
		Initial fee Rs. 8000/- endorsed on 26.04.2011. Differential fee: Fee paid Rs. 12000/- vide Slip No. 0081291 dated 20-10-		
		2014. Duplicate Dossier:		
		Dy No. 32481 dated 11.11.2022		
	Pharmacological Group	Retinoids for topical use in acne ATC Code: D10AD04		
	Type of Form	Form-5		
	Finished product Specification	Not mentioned (monograph in BP)		
	Pack size & Demanded Price	10g. Rs. 250/		
	Approval status of product in Reference	Isotrex Gel isotretinoin 0.05% w/w (0.05 g per 100 g gel).		
	Regulatory Authorities	MHRA Approved.		
	Me-too status	Isotin gel Reg. No. 041923 M/s Shaigan Pharmaceutical (Pvt.) ltd. Rawalpindi.		
	GMP status	Inspection conducted on 14.09.2021. GMP status is good.		
	Remarks of the Evaluator	i. Reference of finished product specifications is not provided.		
	Decision: Approved with BP Specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.			
465.		M/s Pacific Pharmaceuticals Ltd. 30KM Multan Road, Lahore (DML No. 000295)		
	Brand Name + Dosage Form + Strength	Tablet (general) Section. Melomin XR 500mg Tablet		
	Composition	Each extended release tablet contains; Metformin HCl500mg		
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u>		

	Dy. No. 4777 dated 27.4.2011 R&I verified.	
	Initial fee Rs. 15000/- endorsed on 07.04.2011.	
	<u>Differential fee:</u>	
	Fee paid Rs. 5000/- vide Slip No. 0784135 dated 23-10-	
	2018, endorsement 25.10.2018.	
	<u>Duplicate Dossier:</u>	
	Dy No. 32483 dated 11.11.2022	
Pharmacological Group	Biguanides	
	ATC Code: A10BA02	
Type of Form	Form-5	
Finished product Specification	Not mentioned (monograph in USP)	
Pack size & Demanded Price	10g. Rs. 250/	
Approval status of product in Reference	Metformin Teva SR 500 mg, 750 mg and 1000 mg	
Regulatory Authorities	prolonged-release tablets (metformin hydrochloride) - PL	
	00289/2159-2161; UK/H/6844/001-03/DC	
	MHRA Approved.	
Me-too status	Glucophage XR Tablet 500mg Reg. No. 109987	
	M/s Martin Dow Marker Ltd Quetta.	
GMP status	Inspection conducted on 14.09.2021. GMP status is good.	
Remarks of the Evaluator	i. Reference of finished product specifications is not	
	provided.	
Decision: Approved with USP Spec	cifications. The firm shall submit fee of Rs. 7,500/- for	
Decision approved the Col Specifications and shall submit let of Ms. 1,500/- 101		

correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP

Agenda of Evaluator PEC-X

Case no. 01 Registration applications of newly granted DML (Veterinary)

a. New Cases

I. M/s Acme Pharmaceuticals, Rawat, Islamabad.

dated 07-05-2021, before issuance of registration letter.

CLB in its 289th meeting held on 23rd January, 2023 has considered and approved the grant of DML by way of formulation with following sections.

- 1. Oral Dry Powder-I
- 2. Oral Dry Powder-II
- 3. Oral Liquid-I
- 4. Oral Liquid-II

Accordingly, firm has applied for following products for consideration by the Registration Board.

Section	No. of Products	No. of Molecules
	applied	applied
Oral Liquid-I	30	10
Oral Liquid-II	23	10
Oral Dry Powder-II	20	10

Oral Liquid-I			
	(30 Products/ 10 Molecules)		
466.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,	
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,	
		Islamabad	
	Brand Name +Dosage Form +	Mectiver Plus Oral Drench	
	Strength		

	Composition	Each ml contains:
	Composition	Ivermectin0.8mg
	Diary No. Date of R& I & fee	Dy.No 6854 dated 10-03-2023 Rs.30,000/- dated 09-03- 2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Ivotek Drench of M/s Star Labs Lahore (Reg. No. 026541)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
467.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
1071	Applicant Applicant	Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Mectiver Oral Drench
	Composition	Each ml contains:
		Ivermectin10mg
	Diary No. Date of R& I & fee	Dy.No 6853 dated 10-03-2023 Rs.30,000/- dated 09-03- 2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Ivotek Drench of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 062141)
	GMP status	New DML
	Remarks of the Evaluator ^X	
	Decision: Approved.	
468.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Mectiver Super Oral Drench
	Composition	Each ml contains: Ivermectin0.24%
	Diary No. Date of R& I & fee	Dy. No 6855 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Elvomec Drench 0.24% of M/s Elko Organization (Pvt) Ltd., Karachi. (Reg. No. 063730)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
469.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fexazol Plus Oral Drench

	Camara War	F. d. ad continu
	Composition	Each ml contains:
		Oxfendazole25mg
		Cobalt Sulphate2mg
	D' N D (CD0 I 0 C	Sodium Selenite0.5mg
	Diary No. Date of R& I & fee	Dy.No 6849 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anthelmintic/ Antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Could not be confirmed
	GMP status	New DML
	Remarks of the Evaluator X	Shortcomings:
	Remarks of the Evaluator	9
		Evidence of applied formulation/drug already approved DRAP
		by DRAP (generic / me-too status) alongwith
		registration number, brand name and name of firm.
		evidence of applied formulation/drug already approved by
450		with registration number, brand name and name of firm.
470.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,
		Islamabad
	Brand Name +Dosage Form +	Fexazol SC Oral Drench
	Strength	
	Composition	Each ml contains:
		Oxfendazole22.65mg
		Cobalt Sulphate3.82mg
		Sodium Selenite0.35mg
	Diary No. Date of R& I & fee	Dy.No 6848 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anthelmintic/ Antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Oxfendacon Plus Drench of M/s Vetcon Pharmaceuticals (Pvt) Ltd, Bhimber, Azad Jamu Kashmir (Reg. No.
	G) (D	057194)
	GMP status	New DML
	Remarks of the Evaluator X	
4=1	Decision: Approved.	N/
471.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat,
	Brand Name +Dosage Form + Strength	Islamabad Acmelev DS Oral Suspension
	Composition	Each ml contains: Oxyclozanide0.3mg
		Levamisole HCl0.15mg
		Sodium Selenite0.038mg
		· ·
	Diam No Data - CD 0 I 0 C	Cobalt Chloride0.035mg
	Diary No. Date of R& I & fee	Dy.No 6861 dated 10-03-2023 Rs.30,000/- dated 08-03-
		2023
	Pharmacological Group	Anthelmintic
	Type of Form Finished product Specification	Form 5
•		As per innovator's specifications

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474.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,		
7/4.	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,		
	Applicant	Islamabad		
	Brand Name +Dosage Form +	Acmelev SC Oral Suspension		
	Strength	remelev be of a buspension		
	Composition	Each ml contains:		
	Composition	Oxyclozanide60mg		
		Levamisole HCl30mg		
		Sodium Selenite0.7mg		
		Cobalt Chloride1.5mg		
	Diary No. Date of R& I & fee	Dy.No 6858 dated 10-03-2023 Rs.30,000/- dated 08-03-		
	Diary No. Date of R& 1 & fee	2023		
	Pharmacological Group	Anthelmintic		
	Type of Form	Form 5		
	Finished product Specification	As per innovator's specifications		
		30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L,		
	Pack size & Demanded Price	5L: Decontrolled		
		Roldzen Super Suspension of M/s Haarolds		
	Me-too status	Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg.		
	THE too states	No.109067)		
	GMP status	New DML		
	Remarks of the Evaluator X	TWW DIVIE		
	Decision: Approved.			
475.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,		
475.	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,		
	ripplicalit	Islamabad		
	Brand Name +Dosage Form +	Acmelev Plus Oral Suspension		
	Strength	Action of the Suspension		
	Composition	Each ml contains:		
	Composition	Oxyclozanide30mg		
		Levamisole HCl15mg		
		Sodium Selenite0.5mg		
		Cobalt Chloride1.67mg		
	Diary No. Date of R& I & fee	Dy.No 6857 dated 10-03-2023 Rs.30,000/- dated 08-03-		
	Diary No. Date of R& 1 & Ice	2023		
	Pharmacological Group	Anthelmintic		
	Type of Form	Form 5		
	Finished product Specification	As per innovator's specifications		
		30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L,		
	Pack size & Demanded Price	5L: Decontrolled		
		Roldzen PL Oral Suspension of M/s Haarolds		
	Me-too status	Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg.		
	THE too status	No.109065)		
	GMP status	New DML		
	Remarks of the Evaluator X	TWW DIVIL		
	Decision: Approved.			
476.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,		
7/0.	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,		
	1 ppricuit	Islamabad		
	Brand Name +Dosage Form +	Acmelev Oral Suspension		
		Achielev Oral Suspension		
	Strength	Each ml contains:		
	Composition			
		Oxyclozanide30mg		
		Levamisole HCl15mg		
		Sodium Selenite0.35mg		
		Cobalt Chloride0.75mg		

	Diary No. Date of R& I & fee	Dy.No 6856 dated 10-03-2023 Rs.30,000/- dated 08-03-2023	
	Pharmacological Group	Anthelmintic	
	Type of Form	Form 5	
	Finished product Specification	As per innovator's specifications	
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled	
	Me-too status	Nilzole Liquid of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No.034545)	
	GMP status	New DML	
	Remarks of the Evaluator X		
	Decision: Approved.		
477.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad	
	Brand Name +Dosage Form + Strength	Acetil Oral Liquid	
	Composition	Each ml contains: Tilmicosin250mg	
	Diary No. Date of R& I & fee	Dy.No 6844 dated 10-03-2023 Rs.30,000/- dated 08-03-2023	
	Pharmacological Group	Anthelmintic	
	Type of Form	Form 5	
	Finished product Specification	As per innovator's specifications	
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled	
	Me-too status	Tilmic Oral Solution of M/s Biogen Pharma, Rawat Chak Beli Road, Rawat (Reg. No. 063809)	
	GMP status	New DML	
	Remarks of the Evaluator X		
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.		
478.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad	
	Brand Name +Dosage Form + Strength	Ofloxa-10 Oral Liquid	
	Composition	Each ml contains: Ofloxacin100mg	
	Diary No. Date of R& I & fee	Dy.No 6877 dated 10-03-2023 Rs.30,000/- dated 08-03-2023	
	Pharmacological Group	Antibiotic	
	Type of Form	Form 5	
	Finished product Specification	As per innovator's specifications	
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled	
	Me-too status	Oflobak Liquid of M/s Attabak Pharmaceuticals Islamabad (Reg. No. 063829)	
	GMP status	New DML	
	Remarks of the Evaluator ^X		
	Decision: Approved.		
479.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad	
	I		

	Brand Name +Dosage Form +	Acmeflor-20 Oral Liquid
	Strength	Activitor-20 Oral Elquid
	Composition	Each ml contains: Florfenicol200mg
	Diama No. Data of D.C. I. C. for	
	Diary No. Date of R& I & fee	Dy.No 6867 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	I-Enicol Solution of M/s International Pharma Labs, Lahore. (Reg. No. 112298)
	GMP status	New DML
	Remarks of the Evaluator ^X	
	Decision: Approved.	
480.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmeflor-10 Oral Liquid
	Composition	Each ml contains: Florfenicol100mg
	Diary No. Date of R& I & fee	Dy.No 6868 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Maxi-Flor Liquid of M/s Biogen Pharma, Rawat. (Reg. No. 075612)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
481.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmeflor-23 Oral Liquid
	Composition	Each ml contains: Florfenicol230mg
	Diary No. Date of R& I & fee	Dy.No 6869 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Neflox Solution of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 049647)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	

482.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmeflor-25 Oral Liquid
	Composition	Each ml contains: Florfenicol250mg
	Diary No. Date of R& I & fee	Dy.No 6870 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Florfenicol Oral Liquid of M/s Attabak Pharmaceuticals, Islamabad (Reg. No. 075707)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
483.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form +	Cobraflox Oral Liquid
	Strength	
	Composition	Each ml contains: Enrofloxacin100mg
		Colistin Sulphate0.5 MIU Bromhexine HCl50mg
	Diary No. Date of R& I & fee	Dy.No 6846 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic/ benzylamine
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Inter Flox Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 078241)
	GMP status	New DML
	Remarks of the Evaluator X	Shortcomings:
		• The firm shall submit fee of Rs. 7500/- for
		correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP
	T	dated 07-05-2021
	in pharmacological group as per not	ubmit fee of Rs. 7,500/- for correction/pre-approval change ification No.F.7-11/2012-B&A/DRAP dated 07-05-2021
484.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmecoliflox 20/20 Oral Liquid
	Composition	Each ml contains:
	*	Enrofloxacin20%
		Colistin Sulphate0.2 MIU
	Diary No. Date of R& I & fee	Dy.No 6893 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	1 Harmacological Oroup	AHUUUUL

	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	EC Skill-40 Liquid of M/s Bioskils Pharmaceuticals, Sadhoke, District Gujranwala (Reg. No. 111255)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
485.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmecoliflox 10/50 Oral Liquid
	Composition	Each ml contains: Enrofloxacin100mg Colistin Sulphate5,00,00 IU
	Diary No. Date of R& I & fee	Dy.No 6892 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	New DML
i	Remarks of the Evaluator ^X	Shortcomings:
		Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith
486.	Decision: Deferred for submission of by DRAP (generic / me-too status)	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. of evidence of applied formulation/drug already approved alongwith registration number, brand name and name of
486.	Decision: Deferred for submission of by DRAP (generic / me-too status) of firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. of evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
486.	Decision: Deferred for submission of by DRAP (generic / me-too status) a firm. Name and address of manufacturer / Applicant	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. of evidence of applied formulation/drug already approved alongwith registration number, brand name and name of
486.	Decision: Deferred for submission of by DRAP (generic / me-too status) of firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. of evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmecoliflox 20/3 Oral Liquid Each ml contains:
486.	Decision: Deferred for submission of by DRAP (generic / me-too status) of firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. We will be sufficiently brand name and name of alongwith registration number, brand name and name of along
486.	Decision: Deferred for submission of by DRAP (generic / me-too status) afirm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. of evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmecoliflox 20/3 Oral Liquid Each ml contains: Enrofloxacin20% Colistin Sulphate3% Dy.No 6891 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
486.	Decision: Deferred for submission of by DRAP (generic / me-too status) of firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. of evidence of applied formulation/drug already approved alongwith registration number, brand name and name of
486.	Decision: Deferred for submission of by DRAP (generic / me-too status) of firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. of evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmecoliflox 20/3 Oral Liquid Each ml contains: Enrofloxacin20% Colistin Sulphate3% Dy.No 6891 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Antibiotic Form 5 As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
486.	Decision: Deferred for submission of by DRAP (generic / me-too status) of firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. of evidence of applied formulation/drug already approved alongwith registration number, brand name and name of
486.	Decision: Deferred for submission of by DRAP (generic / me-too status) afirm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. If evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmecoliflox 20/3 Oral Liquid Each ml contains: Enrofloxacin20% Colistin Sulphate3% Dy.No 6891 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Antibiotic Form 5 As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled Enrosir-20 Oral Liquid of M/s Attabak Pharmaceutical
486.	Decision: Deferred for submission of by DRAP (generic / me-too status) if firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. of evidence of applied formulation/drug already approved alongwith registration number, brand name and name of
486.	Decision: Deferred for submission of by DRAP (generic / me-too status) afirm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. of evidence of applied formulation/drug already approved alongwith registration number, brand name and name of

	Drand Name Deceme Form	A amagaliflay 25/50 Oral Liquid
	Brand Name +Dosage Form + Strength	Acmecoliflox 25/50 Oral Liquid
	Composition	Each ml contains:
	Composition	Enrofloxacin250mg
		Colistin Sulphate0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 6890 dated 10-03-2023 Rs.30,000/- dated 08-03-
		2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Vitaflox-C 25% Oral Liquid of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh (Reg. No.079276)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
488.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,
		Islamabad
	Brand Name +Dosage Form + Strength	Acmecoliflox 10/48 Oral Liquid
	Composition	Each ml contains:
		Enrofloxacin100mg
		Colistin Sulphate0.48 MIU
	Diary No. Date of R& I & fee	Dy.No 6894 dated 10-03-2023 Rs.30,000/- dated 08-03-
		2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
		30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L,
	Pack size & Demanded Price	5L: Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	New DML
	Remarks of the Evaluator X	Shortcomings:
		Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration
		number, brand name and name of firm.
		of evidence of applied formulation/drug already approved alongwith registration number, brand name and name of
489.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
TU/•	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,
	ripplicant	Islamabad
	Brand Name +Dosage Form +	Acmecoliflox 20/50 Oral Liquid
	Strength	Achieconnox 20/30 Orai Elquid
	Composition	Each ml contains:
	Composition	Enrofloxacin200mg
		Colistin Sulphate0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 6895 dated 10-03-2023 Rs.30,000/- dated 08-03-
	Diary No. Date of R& T& fee	2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pook size & Domanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L,
	Pack size & Demanded Price	5L: Decontrolled

	Me-too status	Floxicol Oral Liquid of M/s Biogen Pharma Rawat (Reg.
		No. 058966)
	GMP status	New DML
	Remarks of the Evaluator ^X	
400	Decision: Approved.	
490.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmicoliflox 10/52 Oral Liquid
	Composition	Each ml contains: Enrofloxacin100mg Colistin Sulphate0.52 MIU
	Diary No. Date of R& I & fee	Dy.No 6896 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Bioenrocolis Liquid of M/s Elegance Pharmaceutical, Chak Belli, Rawalpindi (Reg. No. 073916)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
491.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
171,	Applicant Applicant	Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmecol-44 Oral Liquid
	Composition	Each ml contains: Colistin Sulphate4.8 MIU
	Diary No. Date of R& I & fee	Dy.No 6886 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Colostine Oral Liquid of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad (Reg. No. 078360)
	GMP status	New DML
	Remarks of the Evaluator ^X	
	Decision: Approved.	
492.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmecol-20 Oral Liquid
	Composition	Each ml contains: Colistin Sulphate200mg
	Diary No. Date of R& I & fee	Dy.No 6885 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications

	Parlacian & Dancarda I Drive	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L,
	Pack size & Demanded Price	5L: Decontrolled
	Me-too status	Avi-Col Oral Liquid of M/s Avicenna Laboratories (Pvt) Ltd., Sheikhupura (Reg. No. 071049)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
493.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmeflox-25 Oral Liquid
	Composition	Each ml Contains: Enrofloxacin0.25mg
	Diary No. Date of R& I & fee	Dy.No 6889 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	•	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml:
	Pack size & Demanded Price	Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	New DML
	Remarks of the Evaluator X	Shortcomings:
		Evidence of applied formulation/drug already approved by
		DRAP (generic / me-too status) alongwith registration
		number, brand name and name of firm.
		f evidence of applied formulation/drug already approved dongwith registration number, brand name and name of
494.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmeflox-20 Oral Liquid
	Composition	Each ml contains: Enrofloxacin200mg
	Diary No. Date of R& I & fee	Dy.No 6888 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Enronoor Fort Oral Liquid of M/s Kohinoor Industries, Sahiwal (Reg. No. 081315)
	GMP status	New DML
	Remarks of the Evaluator ^X	
	Decision: Approved.	
495.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,
	Tippheum	Islamabad
	Brand Name +Dosage Form + Strength	Islamabad Acmeflox-10 Oral Liquid

	Diary No. Date of R& I & fee	Dy.No 6887 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Enrosym Oral Solution of M/s Symans Lahore (Reg. No. 022748)
	GMP status	New DML
	Remarks of the Evaluator ^X	
	Decision: Approved.	
		Oral Liquid-II oducts/ 10 Molecules)
496.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,
	**	Islamabad
	Brand Name +Dosage Form + Strength	Florocol-11 Oral Liquid
	Composition	Each ml contains:
	•	Florfenicol110mg
		Colistin Sulphate0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 6864 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Florfarm Liquid of M/s Farm Aid Group, Haripur (Reg. No. 097997)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
497.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florocol-2.5 Oral Liquid
	Composition	Each ml contains: Florfenicol100mg
	Diary No. Date of R& I & fee	Colistin Sulphate25mg Dy.No 6863 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Co-Flor Liquid of M/s Wimits Pharmaceuticals, Lahore (Reg. No. 078326)
	GMP status	New DML
	Remarks of the Evaluator ^X	
	Decision: Approved.	1
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498.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florocol-25 Oral Liquid
	Composition	Each ml contains: Florfenicol250mg Colistin Sulphate0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 6862 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Tye-Fol Liquid of M/s Farm Aid Group, Haripur (Reg. No. 092176)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
499.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florocol-10 Oral Liquid
	Composition	Each ml contains: Florfenicol100mg Colistin Sulphate0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 6865 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Florobex-C Liquid of M/s Elegance Pharmaceuticals, Chak Belli,Rawalpindi.(Reg. No. 078286)
	GMP status	New DML
	Remarks of the Evaluator ^X	
	Decision: Approved.	
500.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florocol-23 Oral Liquid
	Composition	Each ml contains: Florfenicol230mg Colistin Sulphate0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 6866 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Could not be confirmed in the applied strength

	GMP status	New DML
	Remarks of the Evaluator X	Shortcomings:
		Evidence of applied formulation/drug already approved by
		DRAP (generic / me-too status) alongwith registration
		number, brand name and name of firm.
		f evidence of applied formulation/drug already approved
		alongwith registration number, brand name and name of
	firm.	
501.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,
	D IN D E	Islamabad
	Brand Name +Dosage Form +	Sulflox Plus Oral Liquid
	Strength	Each ml contains:
	Composition	
		Enrofloxacin75mg Sulphamethoxypyridazine50mg
		Sulphamethazine50mg
		Trimethoprim25mg
	Diary No. Date of R& I & fee	Dy.No 6876 dated 10-03-2023 Rs.30,000/- dated 09-03-
	Brary 110. Bate of fee fee	2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
		30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml:
	Pack size & Demanded Price	Decontrolled
	N	Sulphacina Oral Liquid of M/s Bio-Oxime Pharmaceuticals,
	Me-too status	Faisalabad. (Reg. No. 074786)
	GMP status	New DML
	Remarks of the Evaluator X	
		inary drugs to review therapeutic requirement keeping in
	view safety, efficacy and quality para	ameters
502.	view safety, efficacy and quality para Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
502.	view safety, efficacy and quality para	Ameters M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat,
502.	view safety, efficacy and quality para Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
502.	view safety, efficacy and quality para Name and address of manufacturer / Applicant Brand Name +Dosage Form +	Ameters M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat,
502.	view safety, efficacy and quality para Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid
502.	view safety, efficacy and quality para Name and address of manufacturer / Applicant Brand Name +Dosage Form +	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains:
502.	view safety, efficacy and quality para Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg
502.	view safety, efficacy and quality para Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg
502.	view safety, efficacy and quality para Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethazine50mg
502.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethoxypyridazine75mg Trimethoprim25mg
502.	view safety, efficacy and quality para Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethazine50mg
502.	view safety, efficacy and quality para Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethoxypyridazine75mg Trimethoprim25mg Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-
502.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethazine50mg Trimethoprim25mg Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
502.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethoxypyridazine75mg Trimethoprim25mg Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023 Antibiotic
502.	view safety, efficacy and quality para Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethoxypyridazine75mg Trimethoprim25mg Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023 Antibiotic Form 5
502.	view safety, efficacy and quality para Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethoxypyridazine75mg Sulphamethoprim25mg Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023 Antibiotic Form 5 As per innovator's specifications
502.	view safety, efficacy and quality para Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethoxypyridazine75mg Trimethoprim25mg Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023 Antibiotic Form 5 As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml:
502.	view safety, efficacy and quality para Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethoxypyridazine75mg Trimethoprim25mg Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023 Antibiotic Form 5 As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
502.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethoxypyridazine75mg Trimethoprim25mg Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023 Antibiotic Form 5 As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled Cina T.S Oral Suspension of M/s Vety-Care Pharmaceutical
502.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator X	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethazine50mg Trimethoprim25mg Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023 Antibiotic Form 5 As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled Cina T.S Oral Suspension of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No.031456) New DML
502.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator X	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethoxypyridazine75mg Trimethoprim25mg Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023 Antibiotic Form 5 As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled Cina T.S Oral Suspension of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No.031456)
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator * Decision: Referred to EWG on veter view safety, efficacy and quality para	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethoxypyridazine75mg Trimethoprim25mg Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023 Antibiotic Form 5 As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled Cina T.S Oral Suspension of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No.031456) New DML inary drugs to review therapeutic requirement keeping in ameters
502.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator X Decision: Referred to EWG on veter view safety, efficacy and quality para	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethoxypyridazine75mg Trimethoprim25mg Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023 Antibiotic Form 5 As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled Cina T.S Oral Suspension of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No.031456) New DML inary drugs to review therapeutic requirement keeping in ameters M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator * Decision: Referred to EWG on veter view safety, efficacy and quality para	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Sulflox DS Oral Liquid Each ml contains: Enrofloxacin75mg Sulphamethoxypyridazine75mg Sulphamethoxypyridazine75mg Trimethoprim25mg Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023 Antibiotic Form 5 As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled Cina T.S Oral Suspension of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No.031456) New DML inary drugs to review therapeutic requirement keeping in ameters

		Tp. 11 10 171 11
	Brand Name +Dosage Form + Strength	Bromithol Oral Liquid
	Composition	Each ml contains:
		Bromhexine HCl10mg
		Menthol20mg
	Diary No. Date of R& I & fee	Dy.No 6874 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Bromotin Liquid of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No.073999)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
504.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form +	Bromithol Plus Oral Liquid
	Strength	1
	Composition	Each ml contains:
		Bromhexine HCl20mg
		Menthol40mg
	Diary No. Date of R& I & fee	Dy.No 6873 dated 10-03-2023 Rs.30,000/- dated 08-03-
		2023
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Bromo-Plus Liquid of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No. 073917)
	GMP status	New DML
	Remarks of the Evaluator X	Tien Bind
	Decision: Approved.	
505.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
303.	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form +	Broxine-10 Oral Liquid
	Strength	213.mil 13 Gran Enquite
	Composition	Each ml contains:
	Composition	Bromhexine HCl100mg
	Diary No. Date of R& I & fee	Dy.No 6872 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	
	1	Mucolytic Form 5
	Type of Form	
	Finished product Specification Pack size & Demanded Price	As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L,
		5L: Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	New DML
	Remarks of the Evaluator X	Shortcomings:
		

		Evidence of applied formulation/drug already approved by
		DRAP (generic / me-too status) alongwith registration
		number, brand name and name of firm.
	Decision: Deferred for submission o	f evidence of applied formulation/drug already approved
	by DRAP (generic / me-too status) a firm.	alongwith registration number, brand name and name of
506.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,
		Islamabad
	Brand Name +Dosage Form +	Broxine-5 Oral Liquid
	Strength	•
	Composition	Each ml contains:
		Bromhexine HCl50mg
	Diary No. Date of R& I & fee	Dy.No 6871 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Bromit 5% Oral Solution of M/s Wimits Pharmaceuticals, Lahore. (Reg. No. 112386)
	GMP status	New DML
	Remarks of the Evaluator ^X	
	Decision: Approved.	
507.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form +	AG-Flox DS Oral Liquid
	Strength	
	Composition	Each ml contains:
		Enrofloxacin100mg
		Aminophylline100mg
	Diama Na Data af D.O. L.O. fra	Guaiphenesin40mg
	Diary No. Date of R& I & fee	Dy.No 6884 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Ensol-AG Oral Liquid of M/s Biogen Pharma, Rawat (Reg. No. 049720)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
508.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	AG-Flox Oral Liquid
	Composition	Each ml contains:
		Enrofloxacin100mg
		Aminophylline40mg
		Guaiphenesin100mg

	Diary No. Date of R& I & fee	Dy.No 6883 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Thirshed product specification	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml:
	Pack size & Demanded Price	Decontrolled
	Me-too status	Enrophylin Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 080730)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	•
509.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmadek Gold Oral Liquid
	Composition	Each ml contains:
	Composition	Vitamin E (alpha tocopheryl acetate)15mg
		Vitamin A (retinol oily form)2,500 IU
		Vitamin K3 (Menadione)2.5mg
		Vitamin D3 (calcifediol)250 MIU
	Diary No. Date of R& I & fee	Dy.No 6882 dated 10-03-2023 Rs.30,000/- dated 08-03-
	-	2023
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml:
	Pack size & Demanded Price	5 11 1
		Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	Me-too status GMP status	
		Could not be confirmed in the applied strength
	GMP status	Could not be confirmed in the applied strength New DML Shortcomings:
	GMP status	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by
	GMP status	Could not be confirmed in the applied strength New DML Shortcomings:
	GMP status Remarks of the Evaluator X Decision: Deferred for submission or by DRAP (generic / me-too status) a	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration
510	GMP status Remarks of the Evaluator X Decision: Deferred for submission of by DRAP (generic / me-too status) a firm.	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of
510.	GMP status Remarks of the Evaluator X Decision: Deferred for submission or by DRAP (generic / me-too status) a	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat,
510.	GMP status Remarks of the Evaluator X Decision: Deferred for submission of by DRAP (generic / me-too status) a firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form +	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
510.	GMP status Remarks of the Evaluator X Decision: Deferred for submission or by DRAP (generic / me-too status) a firm. Name and address of manufacturer / Applicant	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmadek Oral Liquid Each ml contains:
510.	GMP status Remarks of the Evaluator X Decision: Deferred for submission or by DRAP (generic / me-too status) a firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmadek Oral Liquid Each ml contains: Vitamin E (alpha tocopheryl acetate)5mg
510.	GMP status Remarks of the Evaluator X Decision: Deferred for submission or by DRAP (generic / me-too status) a firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmadek Oral Liquid Each ml contains: Vitamin E (alpha tocopheryl acetate)5mg Vitamin A (retinol oily form)0.03 MIU
510.	GMP status Remarks of the Evaluator X Decision: Deferred for submission or by DRAP (generic / me-too status) a firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmadek Oral Liquid Each ml contains: Vitamin E (alpha tocopheryl acetate)5mg Vitamin A (retinol oily form)0.03 MIU Vitamin K3 (Menadione)0.600mg
510.	GMP status Remarks of the Evaluator X Decision: Deferred for submission or by DRAP (generic / me-too status) a firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmadek Oral Liquid Each ml contains: Vitamin E (alpha tocopheryl acetate)5mg Vitamin A (retinol oily form)0.03 MIU Vitamin K3 (Menadione)0.600mg Vitamin D3 (calcifediol)0.001 MIU Dy.No 6881 dated 10-03-2023 Rs.30,000/- dated 08-03-
510.	GMP status Remarks of the Evaluator X Decision: Deferred for submission or by DRAP (generic / me-too status) a firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmadek Oral Liquid Each ml contains: Vitamin E (alpha tocopheryl acetate)5mg Vitamin A (retinol oily form)0.03 MIU Vitamin K3 (Menadione)0.600mg Vitamin D3 (calcifediol)0.001 MIU
510.	GMP status Remarks of the Evaluator X Decision: Deferred for submission or by DRAP (generic / me-too status) a firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmadek Oral Liquid Each ml contains: Vitamin E (alpha tocopheryl acetate)5mg Vitamin A (retinol oily form)0.03 MIU Vitamin K3 (Menadione)0.600mg Vitamin D3 (calcifediol)0.001 MIU Dy.No 6881 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
510.	GMP status Remarks of the Evaluator X Decision: Deferred for submission of by DRAP (generic / me-too status) a firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmadek Oral Liquid Each ml contains: Vitamin E (alpha tocopheryl acetate)5mg Vitamin A (retinol oily form)0.03 MIU Vitamin K3 (Menadione)0.600mg Vitamin D3 (calcifediol)0.001 MIU Dy.No 6881 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Multivitamins Form 5
510.	GMP status Remarks of the Evaluator X Decision: Deferred for submission or by DRAP (generic / me-too status) a firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmadek Oral Liquid Each ml contains: Vitamin E (alpha tocopheryl acetate)5mg Vitamin A (retinol oily form)0.03 MIU Vitamin K3 (Menadione)0.600mg Vitamin D3 (calcifediol)0.001 MIU Dy.No 6881 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Multivitamins Form 5 As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml:
510.	GMP status Remarks of the Evaluator X Decision: Deferred for submission or by DRAP (generic / me-too status) a firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmadek Oral Liquid Each ml contains: Vitamin E (alpha tocopheryl acetate)5mg Vitamin A (retinol oily form)0.03 MIU Vitamin K3 (Menadione)0.600mg Vitamin D3 (calcifediol)0.001 MIU Dy.No 6881 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Multivitamins Form 5 As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
510.	GMP status Remarks of the Evaluator X Decision: Deferred for submission of by DRAP (generic / me-too status) a firm. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification	Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmadek Oral Liquid Each ml contains: Vitamin E (alpha tocopheryl acetate)5mg Vitamin A (retinol oily form)0.03 MIU Vitamin K3 (Menadione)0.600mg Vitamin D3 (calcifediol)0.001 MIU Dy.No 6881 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Multivitamins Form 5 As per innovator's specifications 30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml:

511.		 Shortcomings: Clarification regarding applied strength since Vitamin E5000mg/1000ml is mentioned on cover letter while Vitamin E600mg/1000ml is mentioned in label claim on Form-5. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. f evidence of applied formulation/drug already approved alongwith registration number, brand name and name of M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad Acmadek Super Oral Liquid
	Strength Composition	Each ml contains: Vitamin E (alpha tocopheryl acetate)4mg Vitamin A (retinol oily form)10,000 IU Vitamin K3 (Menadione)2mg Vitamin D3 (calcifediol)2,000 IU
	Diary No. Date of R& I & fee	Dy.No 6880 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Symodex Oral Liquid of M/s Biogen Pharma, Rawat. (Reg. No. 080144)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
512.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Bendol Plus 3% Oral Suspension
	Composition	Each ml contains: Albendazole3% Cobalt Chloride0.050% Sodium Selenite0.030%
	Diary No. Date of R& I & fee	Dy.No 6879 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Anthelmintic/ antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Bendzole 3% Suspension of M/s Attabak Pharmaceuticals Islamabad (Reg. No. 063819)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
513.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad

	D IN D E	D 11D 270/ O 10
	Brand Name +Dosage Form + Strength	Bendol Plus 2.5% Oral Suspension
	Composition	Each ml contains:
	T	Albendazole25mg
		Cobalt Chloride0.75mg
		Sodium Selenite0.35mg
	Diary No. Date of R& I & fee	Dy.No 6878 dated 10-03-2023 Rs.30,000/- dated 08-03-
		2023
	Pharmacological Group	Anthelmintic/ antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
		30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L,
	Pack size & Demanded Price	5L: Decontrolled
		Soletin Oral Suspension of M/s Aamster Laboratories,
	Me-too status	Islamabad (Reg. No. 101436)
	GMP status	New DML
	Remarks of the Evaluator X	New DIVIL
	Decision: Approved.	
514.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,
İ		Islamabad
	Brand Name +Dosage Form +	Acmefenda Plus Oral Drench
	Strength	
	Composition	Each ml contains:
	Composition	Oxyclozanide94mg
		Oxfendazole34mg
		<u>C</u>
		Cobalt Sulphate3.82mg
		Sodium Selenite0.5mg
	Diary No. Date of R& I & fee	Dy.No 6852 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anthelmintic/ antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	•	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml:
	Pack size & Demanded Price	Decontrolled
		Combiox Drench of M/s Selmore Pharmaceuticals (Pvt) Ltd
	Me-too status	Lahore (Reg. No. 057004)
	CMD status	New DML
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
515.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,
		Islamabad
	Brand Name +Dosage Form +	Acmefenda Super Oral Drench
	Strength	Tremerenda super star Brenen
	Composition	Each ml contains:
	Composition	
		Oxyclozanide62.50gm
		Oxfendazole25mg
		Cobalt Sulphate2mg
		Sodium Selenite0.5mg
	Diary No. Date of R& I & fee	Dy.No 6851 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anthelmintic/ antiprotozoal agent
	Type of Form	Form 5
		As per innovator's specifications
	Finished broduler Sheeringshop	
	Finished product Specification	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml:

	Me-too status	Nidozole Drench of M/s Haarolds Pharmaceuticals (Pvt)
	CMD status	Ltd Bhimber, AJK (Reg. No. 109084) New DML
	GMP status Remarks of the Evaluator X	New DML
516.	Decision: Approved. Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmefenda Oral Drench
	Composition	Each ml contains: Oxyclozanide62.50gm Oxfendazole22.65mg Cobalt Sulphate1.67mg
	Diary No. Date of R& I & fee	Sodium Selenite0.5mg Dy.No 6850 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Anthelmintic/ antiprotozoal agent
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Cloxa Gold Drench of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 046669)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
517.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Aceoxol Oral Liquid
	Composition	Each ml contains: Oxolinic Acid100mg
	Diary No. Date of R& I & fee	Dy.No 6847 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Vety Oxol Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 046668)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
518.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Peflo-10 Oral Liquid
	Composition	Each ml contains: Pefloxacin Methanse Sulfonate Eq. to Pefloxacin100mg
	Diary No. Date of R& I & fee	Dy.No 6845 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibiotic

	T	F 5
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml:
		Decontrolled
	Me-too status	PEF-Rold Oral Liquid of M/s Haarolds Pharmaceuticals
		(Pvt) Ltd., Bhimber, AJK. (Reg. No. 109062)
	GMP status	New DML
	Remarks of the Evaluator ^X	
	Decision: Approved.	
	Ora	al Dry Powder-II
	(20 pro	ducts/ 10 Molecules)
519.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,
		Islamabad
	Brand Name +Dosage Form +	Acme-Flush WSP
	Strength	
	Composition	Each gram contains:
		Furosemide20mg
		Sodium Chloride35mg
		Potassium Chloride4mg
		Calcium Carbonate45mg
		Magnesium Sulphate35mg
		Manganese Sulphate1mg
	Diary No. Date of R& I & fee	Dy.No 6820 dated 10-03-2023 Rs.30,000/- dated 09-03-
		2023
	Pharmacological Group	Vitamin/Diuretic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
		Farsolyte Oral Powder of M/s Farm Aid Group, Hattar.
	Me-too status	(Reg. No. 044999)
	GMP status	New DML
	Remarks of the Evaluator X	Shortcomings:
	Remarks of the Evaluator	• The firm shall submit fee of Rs. 7,500/- for
		correction/pre-approval change in pharmacological
		group as per notification No.F.7-11/2012-B&A/DRAP
		dated 07-05-2021
	Decision: Approved The firm shall st	ubmit the Fee of Rs. 30,000/- for correction in formulation
		rmacological group, as per notification No.F.7-11/2012-
	B&A/DRAP dated 07-05-2021 before	
520.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
320.	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,
	Applicant	Islamabad
	Prand Nama Dosaga Form	Acme NOC Water Soluble Powder
	Brand Name +Dosage Form + Strength	Achie NOC water Soluble Fowder
	Composition	Each gram contains:
	Composition	Each gram contains: Oxytetracycline HCl200mg
		Neomycin Sulphate200mg
	Diam, No. Data of D.C. I. C. for	Colistin Sulphate0.24 MIU
	Diary No. Date of R& I & fee	Dy.No 6804 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Dharmagalagigal Crown	Antibacterial
	Pharmacological Group	Form 5
	Type of Form	
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg:
		Decontrolled

Me-too status			Stingulatin 24 Water Soluble Dovider of M/s Houselds
GMP status New DML		Mo too status	Stiagulstin 24 Water Soluble Powder of M/s Haarolds
GMP status New DML		Wie-too status	
Remarks of the Evaluator N Decision: Approved.		CMD status	/
Decision: Approved. Name and address of manufacturer / Applicant Arma			New DIVIL
Name and address of manufacturer / Applicant			
Applicant Brand Name +Dosage Form + Strength Composition Brand Name +Dosage Form + Strength Composition Each gram contains: Oxytetracycline HC1250mg Neomycin Sulphate250mg Colistin Sulphate0.3MIU Diary No. Date of R& I & fee Dy.No 6805 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Antibacterial Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Brand Name +Dosage Form + Strength Composition Acme NOC Forte Water Soluble Powder Dy.No 6805 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Antibacterial As per innovator's specifications Sogm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled Oxycof Forte Powder of M/s Attabak Pharmaceutical Islamabad (Reg. No. 071068) M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw. Islamabad Brand Name +Dosage Form + Strength Composition Acme NOC 20/20 Water Soluble Powder Each gram contains: Oxytetracycline HC1200mg Neomycin Sulphate0.55 MIU Diary No. Date of R& I & fee Dy.No 6806 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Antibacterial Type of Form Form 5 Finished product Specification Pack size & Demanded Price Stingulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109137) GMP status New DML Remarks of the Evaluator × Decision: Approved. 523. Name and address of manufacturer / Applicant Approved. 524. M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw. Islamabad Brand Name +Dosage Form + Apra-C Oral Powder Strength Composition Each gram contains:			
Strength Composition Each gram contains: Oxytetracycline HCl250mg Neomycin Sulphate250mg Colistin Sulphate250mg Neomycin Sulphate250mg Neomycin Sulphate250mg Neomycin Sulphate250mg Colistin Sulphate250mg Colistin Sulphate250mg Neomycin Sulphate250mg Colistin Sulphate203mlU Dy.No 6805 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group	521.		Rawat National Industrial Zone, RCCI Estate Rawat,
Oxytetracycline HCL250mg Neomycin Sulphate250mg Colistin Sulphate250mg Colistin Sulphate250mg Colistin Sulphate250mg Diary No. Date of R& I & fee Dy.No 6805 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Antibacterial Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator N Decision: Approved. 522. Name and address of manufacturer / Applicant Composition Each gram contains: Oxytetracycline HCL200mg Neomycin Sulphate200mg Colistin Sulphate200mg Colistin Sulphate200mg Colistin Sulphate200mg Colistin Sulphate200mg Colistin Sulphate200mg Colistin Sulphate205 MIU Diary No. Date of R& I & fee Dy.No 6806 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Antibacterial Type of Form Finished product Specification Pack size & Demanded Price Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) GMP status Remarks of the Evaluator N Decision: Approved. 523. Name and address of manufacturer / Applicant New DML Remarks of the Evaluator N Decision: Approved. 524. M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) GMP status Remarks of the Evaluator N Decision: Approved. 525. Applicant M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains:			Acme NOC Forte Water Soluble Powder
Diary No. Date of R& I & fee 2023 2023 Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator X Decision: Approved. Strength Composition Diary No. Date of R& I & fee 2023 Pharmacological Group Antibacterial Type of Form Finished product Specification Sogm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled Oxycol Forte Powder of M/s Attabak Pharmaceutical Islamabad (Reg. No. 071068) New DML Remarks of the Evaluator X Decision: Approved. S22. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each gram contains: Oxycteracycline HC1200mg Neomycin Sulphate055 MIU Diary No. Date of R& I & fee 2023 Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw. Islamabad Stragulstin 5.5 MIU Diary No. Date of R& I & fee 2023 Pharmacological Group Antibacterial Form 5 Finished product Specification Pack size & Demanded Price Stragulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N. 109137) GMP status Remarks of the Evaluator X Decision: Approved. S23. Name and address of manufacturer / Applicant W/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw. Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains: Dx. Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw. Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains:		Composition	Oxytetracycline HCl250mg Neomycin Sulphate250mg
Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator * Decision: Approved. Strength Composition Diary No. Date of R& I & fee Diary No. Date of Form Finished product Specification Form 5 Form 5 Form 5 Stagulstrial As per innovator's specifications Oxycol Forte Powder of M/s Attabak Pharmaceutical Islamabad (Reg. No. 071068) New DML Remarks of the Evaluator * Decision: Approved. M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains: Oxytetracycline HCl200mg Neomycin Sulphate0.55 MIU Diary No. Date of R& I & fee Dy.No 6806 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Antibacterial Type of Form Finished product Specification Pack size & Demanded Price Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) GMP status Remarks of the Evaluator * Decision: Approved. 523. Name and address of manufacturer / Applicant M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains:		Diary No. Date of R& I & fee	Dy.No 6805 dated 10-03-2023 Rs.30,000/- dated 09-03-
Type of Form Finished product Specification Pack size & Demanded Price Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator * Decision: Approved. Strength Composition Diary No. Date of R& I & fee Pharmacological Group Pharmacological Group Antibacterial Type of Form Finished product Specification Pack size & Demanded Price Stagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw Islamabad Acme NOC 20/20 Water Soluble Powder Strength Composition Diary No. Date of R& I & fee Dy.No 6806 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Antibacterial Type of Form Finished product Specification Pack size & Demanded Price Stagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) Mew DML Remarks of the Evaluator * Decision: Approved. Stagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) Mew DML Remarks of the Evaluator * Decision: Approved. Stagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) Mew DML Remarks of the Evaluator * Decision: Approved. Stagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains:		Pharmacological Group	Antibacterial
Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator X Decision: Approved. 522. Name and address of manufacturer / Applicant Composition Diary No. Date of R& I & fee Dy. No 6806 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Type of Form Pack size & Demanded Price Finished product Specification As per innovator's specifications Sogm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled Oxycol Forte Powder of M/s Attabak Pharmaceutical Islamabad (Reg. No. 071068) New DML Remarks of the Evaluator X Decision: Approved. M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains: Oxytetracycline HCL200mg Neomycin Sulphate0.55 MIU Diary No. Date of R& I & fee Dy. No 6806 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Antibacterial Type of Form Form 5 Finished product Specification As per innovator's specifications Pack size & Demanded Price Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) GMP status New DML Remarks of the Evaluator X Decision: Approved. Stagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains:			Form 5
Pack size & Demanded Price Me-too status Me-too status GMP status Remarks of the Evaluator X Decision: Approved. Strength Composition Diary No. Date of R& I & fee Plarmacological Group Type of Form Pack size & Demanded Price Me-too status Pack of Remarks of the Evaluator X Decision: Approved. Strength Composition Diary No. Date of R& I & fee Sinished product Specification Pack size & Demanded Price Me-too status Decision: Approved. Strangulstin 55 Water Soluble Powder of M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains: Oxytetracycline HCl200mg Neomycin Sulphate055 MIU Diary No. Date of R& I & fee Dy.No 6806 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Antibacterial Type of Form Form 5 Finished product Specification Pack size & Demanded Price Stagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) GMP status Remarks of the Evaluator X Decision: Approved. Stagulstin 55 Water Soluble Powder of M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains:			As per innovator's specifications
Me-too status Islamabad (Reg. No. 071068)			50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg:
GMP status Remarks of the Evaluator X		Me-too status	
Decision: Approved. S22. Name and address of manufacturer / Applicant M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw Islamabad Acme NOC 20/20 Water Soluble Powder		GMP status	
Name and address of manufacturer / Applicant		Remarks of the Evaluator X	
Name and address of manufacturer / Applicant		Decision: Approved.	
Applicant Brand Name +Dosage Form + Strength Composition Each gram contains: Oxytetracycline HCl200mg Neomycin Sulphate200mg Colistin Sulphate0.55 MIU Diary No. Date of R& I & fee Dy.No 6806 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Antibacterial Type of Form Form 5 Finished product Specification Pack size & Demanded Price Stiagulstin 55 Water Soluble Powder of M/s Haarol Me-too status Me-too status New DML Remarks of the Evaluator X Decision: Approved. 523. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Rame Acme NOC 20/20 Water Soluble Powder Acme NOC 20/20 Water Soluble Powder Dy.No 6806 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Antibacterial Porm 5 Finished product Specification As per innovator's specifications Pack size & Demanded Price Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Raw Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains:	522.		M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
Strength Composition Each gram contains: Oxytetracycline HCl200mg Neomycin Sulphate200mg Colistin Sulphate0.55 MIU Diary No. Date of R& I & fee Dy.No 6806 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Antibacterial Type of Form Form 5 Finished product Specification Pack size & Demanded Price Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) GMP status New DML Remarks of the Evaluator X Decision: Approved. 523. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each gram contains:			Rawat National Industrial Zone, RCCI Estate Rawat,
Oxytetracycline HCl200mg Neomycin Sulphate200mg Colistin Sulphate0.55 MIU Diary No. Date of R& I & fee Dy.No 6806 dated 10-03-2023 Rs.30,000/- dated 09-0 2023 Pharmacological Group Antibacterial Type of Form Form 5 Finished product Specification Pack size & Demanded Price Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) GMP status Remarks of the Evaluator X Decision: Approved. Stand Name and address of manufacturer / Applicant M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Rawal Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains:			Acme NOC 20/20 Water Soluble Powder
Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) GMP status Remarks of the Evaluator X Decision: Approved. 523. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Each gram contains:		Composition	Oxytetracycline HCl200mg Neomycin Sulphate200mg
Type of Form Finished product Specification Pack size & Demanded Price Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) GMP status Remarks of the Evaluator X Decision: Approved. 523. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Form 5 As per innovator's specifications Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Rawal Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains:		Diary No. Date of R& I & fee	Dy.No 6806 dated 10-03-2023 Rs.30,000/- dated 09-03-
Type of Form Finished product Specification Pack size & Demanded Price Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) GMP status Remarks of the Evaluator X Decision: Approved. 523. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Form 5 As per innovator's specifications Stogm, 100gm, 250gm, 500gm, 1Kg,: Decontrolled Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. N 109137) M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Rawal Islamabad Brand Name +Dosage Form + Strength Composition Each gram contains:		Pharmacological Group	Antibacterial
Pack size & Demanded Price Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109137) GMP status Remarks of the Evaluator X Decision: Approved. 523. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109137) New DML M/s Acme Pharmaceuticals, Plot No. 29, St. No. SS-2 Rawat National Industrial Zone, RCCI Estate Rawal Islamabad Brand Name +Dosage Form + Apra-C Oral Powder Strength Composition Each gram contains:		Type of Form	Form 5
Pack size & Demanded Price Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109137) GMP status Remarks of the Evaluator X Decision: Approved. 523. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109137) New DML M/s Acme Pharmaceuticals, Plot No. 29, St. No. SS-2 Rawat National Industrial Zone, RCCI Estate Rawal Islamabad Brand Name +Dosage Form + Apra-C Oral Powder Strength Composition Each gram contains:		Finished product Specification	As per innovator's specifications
Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109137) GMP status Remarks of the Evaluator X Decision: Approved. 523. Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Stiagulstin 55 Water Soluble Powder of M/s Haarol Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109137) New DML M/s Acme Pharmaceuticals, Plot No. 29, St. No. SS-2 Rawat National Industrial Zone, RCCI Estate Rawal Islamabad Brand Name +Dosage Form + Apra-C Oral Powder Strength Composition Each gram contains:			50gm, 100gm, 250gm, 500gm, 1Kg,: Decontrolled
GMP status Remarks of the Evaluator X Decision: Approved. Stand Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength Composition New DML New DML New DML M/s Acme Pharmaceuticals, Plot No 29, St No SS-2 Rawat National Industrial Zone, RCCI Estate Rawat Islamabad Apra-C Oral Powder Each gram contains:		Me-too status	Stiagulstin 55 Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No.
Remarks of the Evaluator X Decision: Approved. 523. Name and address of manufacturer / Applicant Rawat National Industrial Zone, RCCI Estate Rawat Islamabad Brand Name +Dosage Form + Apra-C Oral Powder Strength Composition Each gram contains:		GMP status	
Decision: Approved. 523. Name and address of manufacturer / Applicant			
Same and address of manufacturer / Applicant			1
Brand Name +Dosage Form + Apra-C Oral Powder Strength Composition Each gram contains:	523.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat,
Composition Each gram contains:		_	
			Food grow contains:
Paracetamol20mg		Composition	Vitamin C200mg

		D
		Potassium Chloride40mg
		Calcium Carbonate450mg
		Magnesium Sulphate35mg
	Diary No. Date of R& I & fee	Dy.No 6798 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Vitamin/ NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	1 404 522 66 2 6444 646 1146	Paravit-C Water Soluble Powder of M/s D-Maarson
	Me-too status	Pharmaceuticals, Rawat, Islamabad (Reg. No. 074081)
	GMP status	New DML
	Remarks of the Evaluator ^X	
		g Group to review therapeutic requirement keeping in
	view safety, efficacy and quality para	
524.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,
		Islamabad
	Brand Name +Dosage Form + Strength	Acme NOC Water Soluble Powder
	Composition	Each gram contains:
	Composition of the composition o	Oxytetracycline HCl300mg
		Neomycin Sulphate250mg
		Colistin Sulphate0.5 MIU
	Diary No. Date of R& I & fee	Dy.No 6823 dated 10-03-2023 Rs.30,000/- dated 09-03-
	Diary No. Date of R& 1 & Ice	2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
		50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg:
	Pack size & Demanded Price	Decontrolled
	34	Oxyneoriq-C Water Soluble Powder of M/s Baariq
	Me-too status	Pharmaceuticals, Lahore. (Reg. No. 073952)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
525.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
323.	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat,
	Applicant	Islamabad
	Brand Name +Dosage Form +	Acmepro-50 Water Soluble Powder
	Strength	
	Composition	Each gram contains:
		Amprolium HCl500mg
	Diary No. Date of R& I & fee	Dy.No 6799 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anti-protozoal/ Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Pentaprol 50 Powder of M/s Neotech Pharmaceuticals (Pvt) Ltd. Kamoke (Reg. No.111414)
	GMP status	New DML
	Remarks of the Evaluator X	New DIVIL
<u></u>	Decision: Approved.	

526.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,
520.		Rawat National Industrial Zone, RCCI Estate Rawat,
	Applicant	Islamabad
	Brand Name +Dosage Form +	Acmentadin 10% Water Soluble Powder
	Strength	Tementadin 10/0 Water Soldole I Owder
	Composition	Each gram contains:
	- County County	Amantadine HCl100mg
	Diary No. Date of R& I & fee	Dy.No 6824 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anti-viral
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Amancin-10 Powder of M/s Elegance Pharmaceuticals,
		Distt. Rawalpindi (Reg. No. 112234)
	GMP status	New DML
	Remarks of the Evaluator X	
	_	ng Group to review therapeutic requirement keeping in
527.	view safety, efficacy and quality part. Name and address of manufacturer /	
541.	Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat,
	Applicant	Islamabad
	Brand Name +Dosage Form +	Acmentadin 98% Water Soluble Powder
	Strength	Tementalii 90% Water Soldole I owder
	Composition	Each gram contains:
	- County County	Amantadine HCl0.980gm
	Diary No. Date of R& I & fee	Dy.No 6825 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anti-viral
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Vety Amantex 98% Oral Powder of M/s Leads Pharma (Pvt)
	Me-too status	Ltd., Islamabad (Reg. No. 094402)
	GMP status	New DML
	Remarks of the Evaluator X	
	-	ng Group to review therapeutic requirement keeping in
	view safety, efficacy and quality par	
528.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form +	Florotet 15/15 Oral Powder
	Strength	
	Composition	Each gram contains:
		Oxytetracycline HCl150mg
		Florfenicol150mg
	Diary No. Date of R& I & fee	Dy.No 6828 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg:
	I Pack cize Xt Damandad Price	
	1 ack size & Demanded Title	Decontrolled
	Me-too status	Decontrolled Ox-Keyan 30 Water Soluble Powder of M/s Kayans Pharmaceuticals, Rawalpindi. (Reg. No. 111379)

	Remarks of the Evaluator X	
	Decision: Approved.	
529.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florotet 30/30 Oral Powder
	Composition	Each gram contains: Oxytetracycline HCl300mg Florfenicol300mg
	Diary No. Date of R& I & fee	Dy.No 6829 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Ox-Keyan 60 Water Soluble Powder of M/s Kayans Pharmaceuticals, Rawalpindi. (Reg. No. 111380)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
530.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmepro-90 Water Soluble Powder
	Composition	Each gram contains: Amprolium HCl900mg
	Diary No. Date of R& I & fee	Dy.No 6834 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anti-protozoal/ Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Mak Amprolium Powder of M/s Medicure Laboratories, Karachi. (Reg. No.063609)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
531.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmetet-N 2.5 Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl250mg Neomycin Sulphate150mg
	Diary No. Date of R& I & fee	Dy.No 6841 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	New DML

	Remarks of the Evaluator ^X	Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration	
		number, brand name and name of firm. of evidence of applied formulation/drug already approved alongwith registration number, brand name and name of	
532.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad	
	Brand Name +Dosage Form + Strength	Acmetet-N 10 Water Soluble Powder	
	Composition	Each gram contains: Oxytetracycline HCl100mg Neomycin Sulphate100mg	
	Diary No. Date of R& I & fee	Dy.No 6842 dated 10-03-2023 Rs.30,000/- dated 09-03-2023	
	Pharmacological Group	Antibacterial	
	Type of Form	Form 5	
	Finished product Specification	As per innovator's specifications	
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled	
	Me-too status	Could not be confirmed in the applied strength	
	GMP status	New DML	
	Remarks of the Evaluator X	Shortcomings:	
		Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.		
533.	Name and address of manufacturer /	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22,	
	Applicant	Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad	
	Brand Name +Dosage Form + Strength		
	Brand Name +Dosage Form +	Islamabad Acmetet-N 1.5 Water Soluble Powder Each gram contains: Oxytetracycline HCl15mg	
	Brand Name +Dosage Form + Strength	Islamabad Acmetet-N 1.5 Water Soluble Powder Each gram contains:	
	Brand Name +Dosage Form + Strength Composition	Islamabad Acmetet-N 1.5 Water Soluble Powder Each gram contains: Oxytetracycline HCl15mg Neomycin Sulphate15mg Dy.No 6843 dated 10-03-2023 Rs.30,000/- dated 08-03-	
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Islamabad Acmetet-N 1.5 Water Soluble Powder Each gram contains: Oxytetracycline HCl15mg Neomycin Sulphate15mg Dy.No 6843 dated 10-03-2023 Rs.30,000/- dated 08-03-2023	
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Islamabad Acmetet-N 1.5 Water Soluble Powder Each gram contains: Oxytetracycline HCl15mg Neomycin Sulphate15mg Dy.No 6843 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Antibacterial	
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Islamabad Acmetet-N 1.5 Water Soluble Powder Each gram contains: Oxytetracycline HC115mg Neomycin Sulphate15mg Dy.No 6843 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Antibacterial Form 5	
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification	Islamabad Acmetet-N 1.5 Water Soluble Powder Each gram contains: Oxytetracycline HCl15mg Neomycin Sulphate15mg Dy.No 6843 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Antibacterial Form 5 As per innovator's specifications 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg:	
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	Islamabad Acmetet-N 1.5 Water Soluble Powder Each gram contains: Oxytetracycline HCl15mg Neomycin Sulphate15mg Dy.No 6843 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Antibacterial Form 5 As per innovator's specifications 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled	
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status	Islamabad Acmetet-N 1.5 Water Soluble Powder Each gram contains: Oxytetracycline HCl15mg Neomycin Sulphate15mg Dy.No 6843 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Antibacterial Form 5 As per innovator's specifications 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled Could not be confirmed in the applied strength	
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status	Islamabad Acmetet-N 1.5 Water Soluble Powder Each gram contains: Oxytetracycline HC115mg Neomycin Sulphate15mg Dy.No 6843 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Antibacterial Form 5 As per innovator's specifications 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by	
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status	Islamabad Acmetet-N 1.5 Water Soluble Powder Each gram contains: Oxytetracycline HCl15mg Neomycin Sulphate15mg Dy.No 6843 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Antibacterial Form 5 As per innovator's specifications 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration	
	Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator X	Islamabad Acmetet-N 1.5 Water Soluble Powder Each gram contains: Oxytetracycline HC115mg Neomycin Sulphate15mg Dy.No 6843 dated 10-03-2023 Rs.30,000/- dated 08-03-2023 Antibacterial Form 5 As per innovator's specifications 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled Could not be confirmed in the applied strength New DML Shortcomings: Evidence of applied formulation/drug already approved by	

534	NY 1 11 C C /	N/ A DI .: 1 DI . N 00 G. N GG 00
534.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmetet-N 2.2 Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl22.22mg Neomycin Sulphate22.22mg
	Diary No. Date of R& I & fee	Dy.No 6839 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Nexybak Water Soluble Powder of M/s Attabak Pharmaceuticals Islamabad. (Reg. No. 063840)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	
535.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmetet-N 5 Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl50mg Neomycin Sulphate50mg
	Diary No. Date of R& I & fee	Dy.No 6840 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Oxy-N-50 Powder of M/s Symans Pharmaceuticals Lahore (Reg. No. 013685)
	GMP status	New DML
	Remarks of the Evaluator ^X	
	Decision: Approved.	
536.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Florotet-N Forte Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl3mg Neomycin Sulphate1.5mg Florfenicol1mg
	Diary No. Date of R& I & fee	Dy.No 6830 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled

	Ma too status	Eter Neo Oral Powder of M/s Eterna Pharma (Pvt) Ltd.,
	Me-too status	Mirpur, AJK. (Reg. No. 113452)
	GMP status	New DML
	Remarks of the Evaluator X	
	Decision: Approved.	INC. A. Physical Rev. Co. G. N. GG 22
537.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Virgocine Water Soluble Powder
	Composition	Each gram contains: Vitamin E5mg Vitamin B32mg L Lysine25mg DL Methionine50mg Choline Chloride100mg Virginiamycin12mg
	Diary No. Date of R& I & fee	Dy.No 6802 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Multivitamins/Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Maji Max Oral Water Soluble Powder of M/s Majestic Pharma, Faisalabad. (Reg. No. 089848)
	GMP status	New DML
	Remarks of the Evaluator X	
=20	Decision: Approved.	
538.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Dairy Booster Water Soluble Powder
	Diary No. Date of R& I & fee	Each gram contains: Vitamin A0.8mg Vitamin D30.16mg Vitamin E0.38mg Vitamin B11mg Vitamin B21.25mg Vitamin B120.001mg Vitamin B36.25mg Copper Sulphate0.25mg Magnesium Sulphate25mg Calcium Chloride0.023mg Manganese Sulphate10mg Potassium Iodide0.5mg Sodium Selenite0.01mg DCP150mg Sodium Chloride120mg Vitamin B64mg Zinc Sulphate2.17mg Dy.No 6822 dated 10-03-2023 Rs.30,000/- dated 09-03-
	Pharmacological Group	2023 Multivitamins & Minerals
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	I den size & Demanded I fice	5 55m, 10 5m, 25 55m, 5 0 5m, 1115. Decontrolled

Me-too status	White Gold Powder of M/s Leads Pharma (Pvt) Ltd Islamabad. (Reg. No. 058842)
GMP status	New DML
Remarks of the Evaluator ^X	
Decision: Approved.	

Case No. 1: Registration applications of Human Drugs on form 5F (New DML):

M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi is granted New license on 13/09/2021 and has applied for the following products/molecules.

	1010001001		
539.	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 Finished product manufacturer	Firm has submitted cGMP certificate issued on 22-11-2022 based on inspection conducted on 21-10-2022.	
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 2-10/2011-Lic(Vol-I dated 13/09/2021. Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.	
	Status of application	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	□Domestic sale □ Export sale 図 Domestic and Export sales	
	Dy. No. and date of submission	Dy. No. 1371 dated 16/01/2023	
	Details of fee submitted	PKR 30,000/-: dated 06/01/2023 (Deposit slip#70103647320)	
	The proposed proprietary name / brand name	Neptune 500mg Tablets	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin Hydrochloride equivalent to Ciprofloxacin	
	Pharmaceutical form of applied drug	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	Ciproxin 500mg film-coated Tablets, MHRA Approved.	
	For generic drugs (me-too status)	Ciproxin 500mg Tablet by M/s Bayer Pakistan Private Limited (Reg#107222)	
	Name and address of API manufacturer.	M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km Ferozpur Road, Lahore	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template Summarized information related to nomenclature, structure general properties, solubilities, physical form, manufacturers specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard	

	Module III (Drug Substance) Stability studies Module-III (Drug Product): Pharmaceutical equivalence and comparative dissolution profile Analytical method validation/verification of		container closure system and stability studies of drug substance and drug product is submitted. 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 it verifications, batch analysis and justification of specification details of reference standards, container closure system and stability studies of drug substance.	
			Firm has submitted stability study data as per zone IV-A. 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 6 months Batches: $00510011/001/2014$, $00510011/002/2014$, $00510011/003/2014$	
			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, contained closure system and stability studies of drug product.	
			Firm has submitted results of pharmaceutical equivalence for their product against ciproxin 500mg tablet by M/s Novartis Pharma (mfgr) / Bayer Pakistan (MAH) by performing quality tests (Identification, average weight, disintegration time uniformity of dosage units, dissolution, assay) CDP has been performed against the product ciproxin 500mg tablet by M/s Novartis Pharma (mfgr) / Bayer Pakistan (MAH) 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.	
			Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.	
		STABILIT	ΓΥ STUDY DATA	
Manufacturer of API M/s Pharmagen Limite		ted., Kot Nabi Bukhsh Wala 34-Km, Ferozpur Road, Lahore		
API Lot N	No.	00510011 / 279 / 202	1	
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton		
Stability	Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH		
Time Per	iod	Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T047	T054	T055
Batch Size		1500 tab	1500 tab	1500 tab
Manufacturing Date 16-05-2		16-05-2022	18-05-2022	18-05-2022
Date of Initiation 01-06-2020		01-06-2020	01-06-2020	
No. of Ba	atches		03	
	T .		strative Portion	
1.		evious approval of bility study data of the	Not submitted	
				

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	1 0	Bukhsh Wala 34-Km, For 11-2022 based on ins	Ferozpu spectio
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.	attested respective documents	like chromatograms, Ra	-
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	_		trail
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			
	of Evaluator XI:			_
Section	Observations		Response	
2.3 R 1	Provide copy of Batch Manufacturing Report Provide Copy of Batc	ecord (RMR) for all the batches of		ļ

Section	Observations	Response
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	
3.2.S.4	 Clarification is required as Drug substance manufacturer has given both USP and BP specifications and analytical method while drug product manufacturer has given USP specifications. Clarification is required as the batch number mentioned on COA of drug substance by drug substance manufacturer (00510011 / 279 / 2021) is different than that of drug product manufacturer (00510011 / 280 / 2021) 	
3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.	
3.2.P.5	• Justification is required for not mentioning the time for dissolution test in finished product specifications as recommended by USP.	
3.2.P.8	 Documents for the procurement of API is not submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted 	

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

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540.	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 Finished product manufacturer	Firm has submitted cGMP certificate issued on 22-11-2022 based on inspection conducted on 21-10-2022.	
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13/09/2021. Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.	
	Status of application	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)	

Intended use of pharmaceutical product	□Domestic sale
	☐ Export sale
De Ne en l'aler ef enleurierie	☑ Domestic and Export sales
Dy. No. and date of submission	Dy. No. 1370 dated 16/01/2023
Details of fee submitted	PKR 30,000/-: dated 06/01/2023 (Deposit slip#100252509767)
The proposed proprietary name / brand name	Neptune 250mg Tablets
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin Hydrochloride equivalent to Ciprofloxacin
Pharmaceutical form of applied drug	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 (250mg) film coated tablet, USFDA Approved.
For generic drugs (me-too status)	Ciproxin 250mg Tablet by M/s Bayer Pakistan Private Limited (Reg# 10118)
Name and address of API manufacturer.	M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km Ferozpur Road, Lahore
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template Summarized information related to nomenclature, structure general properties, solubilities, physical form, manufacturers 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 related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verifications, batch analysis and justification of specification details of reference standards, container closure system and stability studies of drug substance.
Stability studies	Firm has submitted stability study data as per zone IV-A. Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 36 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ 6 months Batches: $00510011/001/2014$, $00510011/002/2014$, $00510011/003/2014$
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 results of pharmaceutical equivalence for their product against ciproxin 250mg tablet by M/s Novartis Pharma (mfgr) / Bayer Pakistan (MAH) by performing quality tests (Identification, average weight, disintegration time

uniformity of dosage units, dissolution, assay) CDP has been performed against the product ciproxin 250m tablet by M/s Novariis Pharma (mfgr)/ Bayer plastian (MAH) in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphat Buffer (pH 6.8). The values for f2 are in the acceptable range. Analytical method validation/verification of product STABILITY STUDY DATA Manufacturer of API M/s Pharmagen Limited, Kot Nabi Bukhsh Wala 34-Km, Ferozpur Road, Lahore API Lon No. OS10011 / 279 / 2021 Description of Pack (Container closure system) Stability Storage Condition Real time: 30°C ± 2°C / 65% = 5% 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		T				
Accuracy, precision (repeatability) and Specificity. STABILITY STUDY DATA		i i		CDP has been performed against the product ciproxin 250m tablet by M/s Novartis Pharma (mfgr) / Bayer Pakistan (MAH in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphat		
Manufacturer of API		1	alidation/verification of		·	
API Lot No. 00510011 / 279 / 2021 Description of Pack (Container closure system) Stability Storage Condition Real time: 30°C ± 2°C / 65% ± 5% Accelerated: 40°C ± 2°C / 75% ± 5%RH Time Period Real time: 6 months Accelerated: 6 months Frequency Accelerated: 0, 3, 6 (Months) Batch No. T049 T051 T052 Batch Size 1500 tab 150			STABILIT	TY STUDY DATA		
Description of Pack (Container closure system) Alu-Alu blister packed in unit carton	Manufact	turer of API	M/s Pharmagen Limit	ted., Kot Nabi Bukhsh Wa	ala 34-Km, Ferozpur Road, Lahore	
Container closure system Stability Storage Condition Real time: 30°C ± 2°C / 65% ± 5% RH	API Lot I	No.	00510011 / 279 / 202	1		
Accelerated: 40°C ± 2°C / 75% ± 5%RH Time Period Real time: 6 months Accelerated: 6 months Frequency Accelerated: 0, 3, 6 (Months) Batch No. To49 To51 To52 Batch Size 1500 tab 1500 tab 1500 tab 1500 tab Manufacturing Date 12-05-2022 16-05-2022 16-05-2022 Date of Initiation 01-06-2020 01-06-2020 01-06-2020 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). 4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. 5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing 6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) Remarks of Eyaluator NI;			Alu-Alu blister packe	d in unit carton		
Accelerated: 6 months	Stability	Storage Condition				
Real Time: 0, 3, 6 (Months)	Time Per	iod		S		
Batch Size	Frequenc	у				
Manufacturing Date 12-05-2022 16-05-2022 16-05-2022 Date of Initiation 01-06-2020 01-06-2020 01-06-2020 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). 4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. 5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing 6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) Remarks of Evaluator **I:*	Batch No).	T049	T051	T052	
Date of Initiation No. of Batches O3 Administrative Portion 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. 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. Documents Raw data sheets, COA, summary data sheets etc. Compliance Record of HPLC software 21CFR & audit trail reports on product testing Remarks of Evaluator XI:	Batch Siz	ze	1500 tab	1500 tab	1500 tab	
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). 4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. 5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing 6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) Remarks of Evaluator XI:	Manufact	turing Date	12-05-2022	16-05-2022	16-05-2022	
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). 4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. 5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing 6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) Remarks of Evaluator XI:	Date of I	nitiation	01-06-2020	01-06-2020	01-06-2020	
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) Remarks of Eyaluator XI:	No. of Ba	atches		03		
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) Remarks of Evaluator XI:			Admini	strative Portion		
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) The firm has submitted copy of GMP Certificate of M. Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km, Ferozpu Road, Lahore issued on 22-11-2022 based on inspection conducted on 18-11-2022 valid for two years from date of inspection Not submitted 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 HPLC software 21CFR & audit trail reports on product testing is submitted Remarks of Evaluator XI:	1.	applications with sta		Not submitted		
approval from DRAP (in case of import). 4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. 5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing 6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) Remarks of Evaluator XI:	2.	Approval of API/ DI API manufacturer	issued by concerned	Pharmagen Limited., Ko Road, Lahore issued of conducted on 18-11-20:	t Nabi Bukhsh Wala 34-Km, Ferozpu on 22-11-2022 based on inspectio	
by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. 5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing 6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) Remarks of Evaluator XI:	3.			Not submitted		
21CFR & audit trail reports on product testing is submitted 6. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) Remarks of Evaluator XI:	4.	by attested respective documents like chromatograms, Raw data sheets, COA,		attested respective documents like chromatograms, Raw da		
temperature and humidity monitoring of stability chambers (real time and accelerated) Remarks of Evaluator XI:	5.	21CFR & audit tra				
	6.	temperature and hu stability chambers	imidity monitoring of	Not Submitted		
Section Observations Response	T.					
	Section	Observations			Response	

2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	
3.2.S.4	 Clarification is required as Drug substance manufacturer has given both USP and BP specifications and analytical method while drug product manufacturer has given USP specifications. Clarification is required as the batch number mentioned on COA of drug substance by drug substance manufacturer (00510011 / 279 / 2021) is different than that of drug product manufacturer (00510011 / 280 / 2021) 	
3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.	
3.2.P.5	• Justification is required for not mentioning the time for dissolution test in finished product specifications as recommended by USP.	
3.2.P.8	 The batch number mentioned on chromatograms for assay test at 3rd month time point of real time and accelerated stability study is T047 instead of T049 clarify In real time stability study at 3rd month and 6th month time point of batch#T052, chromatograms of Batch#T051 is submitted instead of Batch#T052, clarify Documents for the procurement of API is not submitted 	
	• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted	

Case No. 2: Registration applications of Human Drugs on form 5F (New Section):

M/s Bio Labs Pvt. Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad has applied for registration of the following products in new section / new license:

M/s Bio Labs Pvt. Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad has applied for registration of the following products in new section of "Dry Vial Injection (General)":

Vancozek 1g Injection

Each vial contains:

Vancomycin HCL for injection eq. to vancomycin1g

Type of form: Form-5F

Dy. No. 34295 dated 28-11-2022 PKR 30,000/-: dated 22-09-2022 (Deposit slip#500444816716)

Remarks:

The applicant, M/s Bio Labs Pvt. Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad is already granted with the above mentioned formulations with the following details;

Vancocin 1000mg Vial

Each vial contains:

Vancomycin HCl for injection eq. to vancomycin.....1g

(USP Specs)

Registration number: 075191

*The registrations of the above mentioned products were granted vide letter No.F.8-6/2012-Reg.III(M-236) dated 08th February, 2013.

The case is hereby placed before the Board.

Decision: Registration Board was apprised that the applicant already hold registration of the above mentioned finished products. The Board discussed that the new applied products contain same formulation as that of already registered products thus the Board decided to reject the applications for Vancozek (Vancomycin HCl) 1g Injection.

Case No. 3: Registration applications of Human Drugs on form 5F (New DML):

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.

S No.	Section	
1.	Capsule Section (General) Section	
2.	Dry Powder Suspension (General) Section	
3.	Sachet (General) Section	
4.	Ampoule (General) Section	
5.	Tablet (General) Section	

Following applications have been submitted for registration by the firm.

542.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer Pharmaceuticals Industries., plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer Pharmaceuticals Industries., plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	 ☑ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021.
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-32/2016-Lic dated 07/06/2021. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and ampoule (general) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	□ Domestic sale□ Export sale⊠ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3117; dated 02/02/2023
	Details of fee submitted	PKR 30,000/-: dated 24/01/2023 (Deposit slip#16971617094)
	The proposed proprietary name / brand name	Krasil Injection 500mg/2ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml vial contains: Amikacin as sulphate BP500mg
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Aminoglycoside Antibiotics
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Amikacin 250mg/ml Injection (500mg/2ml vial), by M/s Hospira UK Limited MHRA approved
	For generic drugs (me-too status)	Zomacin Injection 250mg by M/s Standpharm Pakistan (Reg#23515)

	Name and address of A	PI manufacturer.	M/s Shandong Anxin Pharmaceuti 849, Dongjia Town, Licheng Distr			
	Module-II (Quality Ove	erall Summary)	Firm has submitted QOS as per template. Summarized inform nomenclature, structure, ger solubilities, physical form, description of manufacturing prospecifications, analytical proceeding verification, batch analysis and specification, reference standard, system and stability studies of drug product is submitted.	ation related to neral properties, manufacturers, ocess and controls, cedures and its d justification of container closure		
	Module III (Drug Substance) T st fc p p p ju		The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance			
	Stability studies		Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 48 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months Batches: $(120835205\text{A}, 120835505\text{A}, 120835805\text{A})$			
	Module-III (Drug Product): Pharmaceutical equivalence and comparative dissolution profile		The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.			
			Firm has submitted results of pharmaceutical equivalence for their product against Amikacin by M/s Hospira UK Limited by performing quality tests (Description, acidity, particulate matter, assay, sterility test, bacterial endotoxin)			
	Analytical method value product	lidation/verification of	Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.			
		STABILITY ST	ΓUDY DATA			
Manufac	turer of API	M/s Shandong Anxi Licheng District, Jina	n Pharmaceutical Co. Ltd., No. 84 an, China	49, Dongjia Town,		
API Lot	No.	RA 2014A				
Description of Pack (Container closure system)		type-I, 2mlx1's				
	Stability Storage Condition Real time: $30^{\circ}C \pm 2^{\circ}C$ Accelerated: $40^{\circ}C \pm 1$					
Time Per	riod	Real time: 6 months Accelerated: 6 month				
Frequenc	У	Accelerated: 0, 3, 6 (Real Time: 0, 3, 6 (M				
Batch No).	KS/I-T01	KS/I-T02	KS/I-T03		
Batch Siz	ze	1000 ampoule	1000 ampoule	1000 ampoule		

Manufact	turing Date	03-2022	03-2022	03-2022
9		03-2022	03-2022	03-2022
No. of Batches			03	
		Administrati	ive Portion	
Reference of previous approval of applications with stability study data of the firm (if any)			N/A	
2.	Approval of API/ DML API manufacturer issi regulatory authority of co	ued by concerned	Not submitted	
3.	Documents for the procu approval from DRAP (in		No document submitted	
	attested respective	documents like	supported by attested	data of stability batches respective documents like a sheets, for initial time point ry sheet for six months
5.	Compliance Record of HI & audit trail reports on pr		Not submitted	
	Record of Digital data lo and humidity monitoring (real time and accelerated	of stability chambers	Not submitted	
Remarks	of Evaluator ^{XI} :			
Section	Observations			Response
	• Submit module 1 unattended	of form 5F as mar	y sections are marked	•
1.6.5			of the Drug Substance authority of country of	•
2.3.R.1		uct for which stability	ecord (BMR) for all the v studies data is provided	•
3.2.S.4	substance specifical recommended by BF • Justification is required conditions (mobile particularly temperature, run times substance than that reand BP • Analytical Method accuracy and repeated Drug Product man submitted. • Justification is required specifications or USE.	tions by drug substitutions by drug substitutions by drug substitution, which is a substitution of the commended by drug and the commended by drug the commended by drug substitution studies that it is a substitution of the commended by drug substitution of the commended by drug and the commended by drug substitution of the commended b	test for sulphate in drug stance manufacturer as fferent chromatographic avelength, column oven manufacturer for drug substance manufacturer s including specificity, ision) performed by the substance(s) shall be rug substance follow BP h are mentioned on COA in batch analysis	
3.2.S.5		econdary reference st	andard including source	•
3.2.P.1	Justifications is requ		c acid for pH adjustment for pH adjustment	•
3.2.P.2	• Submit the details of innovator/reference/pharmaceutical equir	of brand name, batch comparator produ valence profile studies red for not performin	No# and expiry date of	•

	• Justification is required since pharmaceutical equivalence studies have not been conducted against the innovator product.	
	• Label claim for applied product mentioned in module 1 of form 5F is vial while primary packaging material is ampoule, clarify	
3.2.P.7	• Applied product is packed in ampoule while reference product is packed in vials, clarify	•
3.2.P.8	 Submit documents for the procurement of API with approval from DRAP Chromatograms, Raw data sheets and COA stability study at 3rd month and 6th month time point not submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted 	•

Case No. 4: Registration applications of Human Drugs on form 5F (New DML):

M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.

The Central Licensing Board 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 seven (07) sections to M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot under Drug Manufacturing License No. 000944 vide approval letter No. F.1-5/2017-Lic dated 17/09/2021. The Drug Manufacturing License No. 000944 by way of formulation is hereby issued w.e.f. 13-09-2021.

S No.	Section			
1.	Tablet (General)			
2.	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)			

Following applications have been submitted for registration by the firm.

543.	Name, address of Applicant / Mar keting Authorization Holder	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.				
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.				
	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. 000944) by way of formulation dated 17-09-2021.				
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-09-2021 which specifies 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. 3131 : 02/02/2023				

Details of fee submitted	PKR 30,000/-: 12/12/2022 (Deposit slip#7485549404)
The proposed proprietary name / brand name	Praq 20mg Capsule
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard gelatine capsule contains: Enteric coated pellets (8.5%) of omeprazole equivaler to omeprazole20mg
Pharmaceutical form of applied drug	Hard gelatine capsule
Pharmacotherapeutic Group of (API)	Proton pump inhibitors
Reference to Finished product specifications	USP
Proposed Pack size	2x7's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Omeprazole 20 mg Gastro-resistant Capsules MHRA Approved
For generic drugs (me-too status)	Risek Capsule 20mg by M/s Getz Pharm (Reg#19364)
Name and address of API manufacturer.	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-Pl template. Firm has summarized information related to nomenclature, structure, general properties solubilities, physical form, manufacturer 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.
Module-III Drug Substance:	Firm has submitted detailed data for drug substant related to nomenclature, structure, general propertie solubilities, physical form, manufacturers, description of manufacturing process and controls, specification analytical procedures and its verifications, batcanalysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	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 month Batches: (OMP073,)
Module-III Drug Product:	Firm has submitted data of drug product including it description, composition, pharmaceutics development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specification analytical procedures, verification of analytical procedures, batch analysis, justification of 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 Risek 20m capsule by performing quality tests (appearance identification, dissolution, assay)

		alytical method v duct	alidation/verification	of	studies including s	speci	vtical method verification ficity, linearity, range, ability), system suitability.
			STABILITY	ST	UDY DATA		
Man	ufactur	er of API	Vision Pharmaceutica Islamabad.	ls P	vt. Ltd, Plot No. 22-23, I	ndus	strial Triangle Kahuta Road
API	Lot No		OMP1199				
		of Pack closure system)	Alu-Alu Blister packe	ed ii	1 unit carton 2x7's		
Stab	oility Sto	orage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2$				
Tim	e Period	1	Real time: 6 months Accelerated: 6 months	s			
Freq	luency		Accelerated: 0, 3, 6 (M) Real Time: 0, 3, 6 (M)		,		
Bato	h No.		T001	T0	02	T00)3
Bato	h Size		658 capsule	65	8 capsule	658	capsule
Man	ufactur	ing Date	04-2022	04	-2022	04-2	2022
Date	of Init	iation	27-04-2022	27	-04-2022	27-0	04-2022
No.	of Batc	hes			03		
	D	OCUMENTS / DATA	A TO BE PROVIDE) A	LONG WITH STABIL	ITY	STUDY DATA
1.		ence of previous appr ity study data of the fir		ith	No reference is submitt	ed by	y the firm
2.	manu		concerned regulate			issu	cGMP certificate of M/s ed on 22-08-2022 based on 06-2022.
3.		ments for the procuren DRAP (in case of imp		val	No document submitted	i	
4.	respec	•	chromatograms, Raw d			locui	stability batches supported ments like chromatograms, mary data sheets etc.
5.	_	oliance Record of HI trail reports on produc	PLC software 21CFR t testing	&	Not submitted		
6.	humic and ac	lity monitoring of stal ccelerated)	gger for temperature a pility chambers (real ti		Submitted		
		Evaluator XI:					Dagmanga
		Observations • Justification is red	nuired for using 2% o	ver	gage in finished product	t as	Response
2.3		mentioned in BMR • Justification shall l pellets against th	quired for using 2% overage in finished product as R be submitted for the dispensed quantity of Omeprazole ne label claim with reference to the potency of ts determined during drug substance analysis by M/s		zole of		

3.2.S.	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(s) shall be submitted. 			
	• Justification shall be submitted for incomplete testing of drug substance by drug product manufacturer as recommended by drug substance manufacturer (loss on drying, sugar test, pellet size, bulk density).			
	• Clarification shall be submitted regarding declared the potency of Omeprazole pellets determined during drug substance analysis by M/s Qadir Pharma whether it is on "as is basis" or "anhydrous basis".			
3.2.S.		•		
3.2.P.	innovator/reference/comparator product against which pharmaceutical equivalence studies have been performed	•		
	 Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP (uniformity of dosage units). Justification is required since pharmaceutical equivalence have not been conducted against the innovator product. 			
	 Submit CDP studies of applied product as per guidelines approved by the registration board in its 293rd meeting 			
3.2.P.	 units in finished product specifications as recommended by USP. Justification is required for not mentioning the test number and time for dissolution test in finished product specifications at buffer stage as 	•		
	recommended by USP. • Signed copies of the Drug product analytical procedures used for routine testing of the Drug product by Drug Product manufacturer is required from M.s Qadir Pharmaceuticals instead of referring to the USP monograph extract.			
3.2.P.		•		
	• Justification is required since results of dissolution test in stability summary sheets at acid stage of batch No#T001 Accelerated conditions at 6 th month time point, T002 Accelerated conditions at 6 th month time point, T003 real time conditions at 3 rd and 6 th month time point show results in terms of negative percentage.			
	• Justification shall be submitted for performing the dissolution test at acid stage on HPLC and at buffer stage on UV spectrophotometer in stability studies			
	• Clarification shall be submitted regarding the calculation formula applied for the results of Acid stage dissolution test with reference to the USP monograph since firm has represented the dissolution results as more than			
	90% in raw data sheets of acid stage dissolution test and has further subtracted results of dissolution test at acid stage from assay test for calculating final results.			
Decisio	Submit document for procurement of API. Registration Board deferred the case for submission of reply to the above	cited shortes	mines	
544.	Name, address of Applicant / Mar keting M/s Qadir Pharmaceutica			
JTT.	Authorization Holder Sahuwala Road, Sialkot.	is, v ceruili	1 aten	Gaill

Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
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. 000944) by way of formulation dated 17-09-2021.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-09-2021 which specifies 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. 5904 : 02/03/2023
Details of fee submitted	PKR 30,000/-: 07/12/2022 (Deposit slip#556684006746)
The proposed proprietary name / brand name	Praq 40mg Capsule
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard gelatine capsule contains: Enteric coated pellets (22.5%) of omeprazole equivalent to omeprazole40mg
Pharmaceutical form of applied drug	Hard gelatine capsule
Pharmacotherapeutic Group of (API)	Proton pump inhibitors
Reference to Finished product specifications	USP
Proposed Pack size	2x7's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Omeprazole 40mg gastro-resistant capsules MHRA Approved
For generic drugs (me-too status)	Risek Capsule 40mg by M/s Getz Pharma (Reg#22109)
Name and address of API manufacturer.	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, 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 data for drug substance related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verifications, batch analysis and justification of specification, reference

			standard, container of drug substance.	losure system and stability studies		
	Stability Studies of Drug (Conditions & duration o		Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm$	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: (OMP065, OMP103, OMP083)		
	Module-III Drug Product	:	description, co development, manufa- process control, pro- of excipients, contro- analytical procedur procedures, batch	rence standard or materials,		
	Pharmaceutical Equival Dissolution Profile	ence and Comparativ	equivalence for the	ed results of pharmaceutical ir product against Risek 40mg ning quality tests (appearance, ution, assay)		
	Analytical method v product	alidation/verification o	studies including	l analytical method verification specificity, linearity, range, repeatability), system suitability.		
		STABILITY S	TUDY DATA			
Manı	ufacturer of API	Vision Pharmaceuticals Islamabad.	Pvt. Ltd, Plot No. 22-23, Industrial Triangle Kahuta Road			
API I	Lot No.	OMP896				
	Description of Pack (Container closure system) Alu-Alu Blister packed in		n unit carton 2x7's			
Stabi	lity Storage Condition	Real time: 30°C ± 2°C / Accelerated: 40°C ± 2°C				
Time	Period	Real time: 6 months Accelerated: 6 months				
Frequ	uency	Accelerated: 0, 3, 6 (MorReal Time: 0, 3, 6 (Mor				
Batch	ı No.	Т001 Т	7002	T003		
Batch	n Size	658 capsule 6	58 capsule	658 capsule		
Manu	ufacturing Date	05-2022	5-2022	05-2022		
Date	of Initiation	03-05-2022	4-05-2022	04-05-2022		
No. c	of Batches		03			
	DOCUMENTS / DAT	A TO BE PROVIDED	ALONG WITH STAB	ILITY STUDY DATA		
1.	Reference of previous appr stability study data of the fi		No reference is subm	itted by the firm		
2.	Approval of API/ DML/omanufacturer issued by authority of country of orig	concerned regulator	The firm have submitted cGMP certificate of M/s Vision Pharmaceuticals issued on 22-08-2022 based on inspection conducted on 14-06-2022.			
3.	Documents for the procurer from DRAP (in case of imp	* *	No document submitt	eed		
4.	I ————————————————————————————————————	chromatograms, Raw dat	Firms has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			

5.		bliance Record of HPLC software 21CFR & trail reports on product testing	The firm submitted that our compliant and audit trail reponot submitted	
6. 	humic and a	d of Digital data logger for temperature and dity monitoring of stability chambers (real time ecclerated)		
	arks o tion	f Evaluator ^{XI} : Observations		Dognanga
2.3.			vancas in finished anadyst as	Response
2.3.	K.1	 Justification is required for using 1.25% or mentioned in BMR Justification shall be submitted for the disperselets against the label claim with reference pellets determined during drug substance ana 	ensed quantity of Omeprazole to the potency of Omeprazole	•
3.2.		 Copies of the Drug substance specifications a for routine testing of the Drug substance by required. Analytical Method Verification studies inclu repeatability (method precision) perform manufacturer for drug substance(s) shall be s Justification shall be submitted for incomplet drug product manufacturer as recomm manufacturer (loss on drying, sugar test, pelle Clarification shall be submitted regardin Omeprazole pellets determined during drug Qadir Pharma whether it is on "as is basis" or 	Drug Product manufacturer is ding specificity, accuracy and ned by the Drug Product ubmitted. The testing of drug substance by nended by drug substance et size, bulk density). The declared the potency of g substance analysis by M/s r "anhydrous basis".	
3.2.	P.2	•		
3.2.	P.5	 registration board in its 293rd meeting Justification is required for not including the units in finished product specifications as rec Justification is required for not mentioning dissolution test in finished product speci recommended by USP. Signed copies of the Drug product analyticatesting of the Drug product by Drug Product M.s Qadir Pharmaceuticals instead of references. 	the test number and time for fications at buffer stage as all procedures used for routine manufacturer is required from	•
3.2.	P.8	 The batch number of manufactured batches in CTR002, CTR003 while batch number menting is T001, T002, T003, clarify Justification is required since results of dissolutions sheets at acid stage of batch No#T003 Acceleration point show results in terms of negative properties. Justification shall be submitted for performing stage on HPLC and at buffer stage on UV studies Clarification shall be submitted regarding the for the results of Acid stage dissolution termonograph since firm has represented the displacements. 	ution test in stability summary erated conditions at 3 rd month percentage. In the dissolution test at acid spectrophotometer in stability are calculation formula applied st with reference to the USP	•

90% in raw data sheets of acid stage dissolution test and has further	
subtracted results of dissolution test at acid stage from assay test for	
calculating final results.	
 • Submit document for procurement of API.	

Agenda of Evaluator PEC-XIII

539.	Name, address of Applicant / Marketing Authorization Holder	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.
	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. 3116; dated 02/02/2023.
	Details of fee submitted	PKR 30,000/-: vide slip No.6901084368 dated 01/08/2022.
	The proposed proprietary name / brand name	Invipam 500mg Injection IM/IV.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine500mg
	Pharmaceutical form of applied drug	Sterile Powder for injection.
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporin. (J01DE)
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1's.
	Proposed unit price	As per policy.
	The status in reference regulatory authorities	MAXIPIME 500mg & 1gm (Cefepime hydrochloride) for injection, USFDA Approved.
	For generic drugs (me-too status)	CefStar for injection 500mg IV/IM, Barret Hodgson Pakistan (Pvt.) Ltd., Registration No: 030953.
	GMP status of the Finished product manufacturer	Last inspection report conducted on 31-08-2022 is submitted wherein the firm was working at good level of GMP.
	Evidence of section approval.	Dry Powder Injection (Cephalosporin) section vide No.F.1-37/2016-Lic (Vol-I) dated 18-02-2022 is approved.

Name and address of API manu	ıfacturer.	M/s Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China. Firm has submitted copy of manufacturing license No. Lu 20150511 valid till 26-10-2015. (Raw materials, Sterile raw materials)		
Module-II (Quality Overall Sur	nmary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, 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 the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures, batch analysis (11C0742107001, Mfg. date 12-07-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.		
Stability studies (Drug substance	ee.)	Firm has submitted both real time and accelerated stability study data for the drug substance for three batches. 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: (11C0741702001, 11C0741702002 & 11C0741702003)		
Module-III (Drug Product):		The firm has submitted detail of the drug product including its description & composition, Pharmaceutical equivalence, 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 equivalen comparative dissolution profile		Pharmaceutical Equivalence is established against the brand leader that is Maxipime 500mg IV/IM injection batch No. Y83J, mfg. date 01-2021 manufactured by GSK, Pakistan by performing quality tests (Identification, water content, pH, bacterial endotoxin, sterility & Assay).		
Analytical method validation/ve		Method verification studies have submitted including linearity, range, accuracy, precision, specificity.		
	STABILIT	Y STUDY DATA		
Co., L		dong Luoxin Pharmaceutical Group Hengxin Pharmaceutical West Side of yanbin Road, Feixian Economic Development ndong, China.		
API Lot No.	Not provide	ed.		
Description of Pack (Container closure system)	stopper and	Type II glass vial filled with powder, closed with rubber flip-off seal.		
Stability Storage Condition	Accelerated	ime: 30°C ± 2°C / 65% ± 5%RH erated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6	5 months		

			Accelerated	: 6 month	ıs		
Freque	ency		Accelerated Real Time:				
Batch No.		TDI001		TDI002	TCH001		
Batch S	Size						
Manufa	acturing Da	ite	11-2	2021	11-2021	11-2021	
Date of	f Initiation		11-2	2021	11-2021	11-2021	
No. of	Batches				03	·	
		REQUEST OF I	EXEMPTIO	N FROM	ON SITE INSPEC	ΓΙΟΝ	
The		quested for Exemption from the conjugate of the conjugate from the con					the
			Administ	trative P	ortion		
1.	firm (i	ations with stability study f any)	y data of the		has not submitted an	•	NI I
2.	API r	val of API/ DML/GMP of manufacturer issued by tory authority of country of	concerned	201505	is submitted copy of 11 valid till 26-10-202 aterials, Sterile raw m		No. Lu
3.	Docum	nents for the procurement val from DRAP (in case o	of API with				
4.	by at	of stability batches will be tested respective docu atograms, Raw data shary data sheets etc.	iments like		Sub	mitted	
5.		liance Record of HPL R & audit trail reports			Not Su	ubmitted	
6.	Record temper stabilit acceler	rature and humidity mo cy chambers (real	00	Not Submitted			
	ks by the Ev						7
Sr. No.	Section	Observations			Reply by the firm		
1.	1.5.2 or 3.2.P.5.1	Label claim of the applie revised as per reference p of full fee.					
2.	1.5.5	Pharmacotherapeutic grof from third generation generation cephalosporin.	cephalosporin				
3.	2.3.	Table for literature refer with inclusion of status of and finished product in ph	ences shall be of both drug s				
4.	3.2.S.4.1	Specifications of the drug substance manufacturer sl	g substance by hall be submitt	ed.			
5.	3.2.S.4.2	Analytical procedures for used by the drug product submitted.					
6.	3.2.S.4.3	Verification studies of performed by the drug shall be submitted.					
7.	3.2.S.7	• Specifications of the dr by the drug substant					

		different from the specification of substance in the stability data Justification shall be submitted. • Specifications of the drug substamentioned "Contains NLT 90% at 115% of Cefepime HCl calculanhydrous and Arginine free basis" stability data sheets for the drug substamentioned "NLT 83% of Cefepime con anhydrous and Arginine free Justification shall be submitted.	sheets. ance has and NMT ated on while the tance has alculated
8.	3.2.P.5.1	Specifications provided by the finished manufacturer for the drug product Lidocaine HCl instead of Cefepime HC arginine. Clarification shall be submitted	cl with L
9.	3.2.P.5.2	Analytical procedures provided by the product manufacturer for the drug prod Lidocaine HCl instead of Cefepime HC arginine. Signed analytical procedures for the drug shall be submitted.	finished uct is for Cl with L
10.	3.2.P.8	 Identification test, water content test performed in the stability studies of product. Stability data sheets shall be as per de 293rd meeting of Registration Bo inclusion of API lot number, date of of stability studies and total batch siz Documents for the procurement of approval from DRAP shall be submit Reference of previous approapplications with stability study dafirm shall be submitted. Compliance Record of HPLC softwar & audit trail reports on product testing submitted. 	ecision of ard with initiation ee. API with tted. oval of ta of the
Decision 540.	Name,	ation Board deferred the case for su address of Applicant / Marketing ization Holder	bmission of reply to the above cited shortcomings. M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.
	Name,	address of Manufacturing site.	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.
	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)
	Intende	ed use of pharmaceutical product	□ Domestic sale□ Export sale☑ Domestic and Export sales
	Dy. No	o. and date of submission	Dy. No. 1853; dated 19/01/2023.
		of fee submitted	PKR 30,000/-: vide slip No.0829772894 dated 01/08/2022.
		roposed proprietary name / brand	Invipam 1000mg Injection IM/IV.

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine1000mg
Pharmaceutical form of applied drug	Sterile Powder for injection.
Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporin. (J01DE)
Reference to Finished product specifications	USP specifications.
Proposed Pack size	1's.
Proposed unit price	As per policy.
The status in reference regulatory authorities	MAXIPIME 500mg, 1gm & 2gm (Cefepime hydrochloride) for injection, USFDA Approved.
For generic drugs (me-too status)	CefStar for injection 1000mg IV/IM, Barret Hodgson Pakistan (Pvt.) Ltd., Registration No: 030954.
GMP status of the Finished product manufacturer	Last inspection report conducted on 31-08-2022 is submitted wherein the firm was working at good level of GMP.
Evidence of section approval.	Dry Powder Injection (Cephalosporin) section vide No.F.1-37/2016-Lic (Vol-I) dated 18-02-2022 is approved.
Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China. Firm has submitted copy of manufacturing license No. Lu 20150511 valid till 26-10-2015. (Raw materials, Sterile raw materials)
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, 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 the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures, batch analysis (11C0742107001, Mfg. date 12-07-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability study data for the drug substance for three batches. 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: (11C0741702001, 11C0741702002 & 11C0741702003)

			The firm has submitted detail of the drug product including its description & composition, Pharmaceutical equivalence, 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 brand leader that is Maxipime 1000mg IV/IM injection batch No. Y83J, mfg. date 01-2021 manufactured by GSK, Pakistan by performing quality tests (Identification, water content, pH, sterility, bacterial endotoxin & Assay).			
	Analytical method validation/ve product	erification of		rification studies have ge, accuracy, precision, sp	•	
		STABILIT	Y STUDY DA	ATA		
Manufactu	irer of API	Co., Ltd.,		Pharmaceutical Group Heryanbin Road, Feixian Eco		
API Lot N	0.	Not provide	ed.			
Description (Container	n of Pack closure system)		Type II glas flip-off seal.	ss vial filled with powde	er, closed with rubber	
Stability St	Stability 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				
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)				
Batch No.		TD	I001	TDI002	TCH001	
Batch Size)					
Manufactu	aring Date	11-	2021	11-2021	11-2021	
Date of Ini	itiation	11-	2021	11-2021	11-2021	
No. of Bat				03		
	-			SITE INSPECTION		
The fire	m has requested for Exemption fro following documents in conju	nction with t	he checklist a	pproved by the Registration		
	T		trative Portio			
1.	Reference of previous applications with stability study firm (if any)	•	The firm has	not submitted any docume	ent.	
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.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			Submitted		

	•	_		
5.		iance Record of HPLC software		
		R & audit trail reports on product	Not Submitted	
	testing			
6.	Record	d of Digital data logger for		
		rature and humidity monitoring of	Not Submitted	
	stabilit	•	1 (of Submitted	
	accelei	rated)		
	ks by the Ev			
Sr.	Section	Observations	Reply by the firm	
No. 1.	1.5.0	Y -1 -1 -1-1-1		
1.	1.5.2 or 3.2.P.5.1	Label claim of the applied formulation shall be revised as per reference product with submission		
	3.2.1 .3.1	of full fee.		
2.	1.5.5	Pharmacotherapeutic group shall be changed		
		from third generation cephalosporin to 4th		
		generation cephalosporin.		
3.	2.3.	Table for literature references shall be revised		
		with inclusion of status of both drug substance and finished product in pharmacopoeia.		
4.	3.2.S.4.1	Specifications of the drug substance by the drug		
''	3.2.5.1.1	substance manufacturer shall be submitted.		
5.	3.2.S.4.2	Analytical procedures for the drug substance		
		used by the drug product manufacturer shall be		
	22712	submitted.		
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer		
		shall be submitted.		
7.	3.2.S.7	• Specifications of the drug substance provided		
		by the drug substance manufacturer are		
		different from the specification of the drug		
		substance in the stability data sheets.		
		Justification shall be submitted.		
		• Specifications of the drug substance has mentioned "Contains NLT 90% and NMT		
		115% of Cefepime HCl calculated on		
		anhydrous and Arginine free basis" while the		
		stability data sheets for the drug substance has		
		mentioned "NLT 83% of Cefepime calculated		
		on anhydrous and Arginine free basis".		
	22771	Justification shall be submitted.		
8.	3.2.P.5.1	Specifications provided by the finished product		
		manufacturer for the drug product is for Lidocaine HCl instead of Cefepime HCl with L		
		arginine. Clarification shall be submitted.		
9.	3.2.P.5.2	Analytical procedures provided by the finished		
		product manufacturer for the drug product is for		
		Lidocaine HCl instead of Cefepime HCl with L		
		arginine.		
		Signed analytical procedures for the drug product shall be submitted.		
10.	3.2.P.8	Identification test, water content tests are not		
		performed in the stability studies of the drug		
		product.		
		Stability data sheets shall be as per decision of		
		293 rd meeting of Registration Board with		
		inclusion of API lot number, date of initiation		
		of stability studies and total batch size.		
		• Documents for the procurement of API with approval from DRAP shall be submitted.		
<u> Ш</u>	1			

Projection	Reference of previous approapplications with stability study da firm shall be submitted. Compliance Record of HPLC softwar & audit trail reports on product testing submitted. Resistant in Record defermed the case for any stability of the stability of	ta of the re 21CFR g shall be	
	_	bmission of reply to the above cited shortcomings.	
541.	Name, address of Applicant / Marketing Authorization Holder	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.	
	Name, address of Manufacturing site.	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.	
	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. 2384; dated 25/01/2023.	
	Details of fee submitted	PKR 30,000/-: vide slip No.91779456 dated 04/08/2022.	
	The proposed proprietary name / brand name	Invipam 2000mg Injection IM/IV.	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine2000mg	
	Pharmaceutical form of applied drug	Sterile Powder for injection.	
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporin. (J01DE)	
	Reference to Finished product specifications	USP specifications.	
	Proposed Pack size	1's.	
	Proposed unit price	As per policy.	
	The status in reference regulatory authorities	MAXIPIME 500mg, 1gm & 2gm (Cefepime hydrochloride) for injection, USFDA Approved.	
	For generic drugs (me-too status)	CefStar for injection 2000mg IV/IM, Barret Hodgson Pakistan (Pvt.) Ltd., Registration No: 089284.	
	GMP status of the Finished product manufacturer	Last inspection report conducted on 31-08-2022 is submitted wherein the firm was working at good level of GMP.	
	Evidence of section approval.	Dry Powder Injection (Cephalosporin) section vide No.F.1-37/2016-Lic (Vol-I) dated 18-02-2022 is approved.	
	Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China. Firm has submitted copy of manufacturing license No. Lu 20150511 valid till 26-10-2015. (Raw materials, Sterile raw materials)	

Module-II (Quality Overall Sun	nmary)	Summarized general prop manufacturin specification justification	s, analytical procedures of specification, referer m and stability studies of	omenclature, structure, acturers, description of controls, impurities, s, batch analysis and ace standard, container	
Module III (Drug Substance)		nomenclatur physical for process and analytical pr date 12-07-2	omitted detail of the drug e, structure, general m, manufacturers, descrip controls, tests for in ocedures, batch analysis 021) and justification of ntainer closure system and	properties, solubility, ption of manufacturing npurity, specifications, (11C0742107001, Mfg. specification, reference	
Stability studies (Drug substance	Stability studies (Drug substance.) Module-III (Drug Product):		Firm has submitted both real time and accelerated stability study data for the drug substance for three batches. 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: (11C0741702001, 11C0741702002 & 11C0741702003) The firm has submitted detail of the drug product including its description & composition, Pharmaceutical equivalence, 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.		
Module-III (Drug Product):					
Pharmaceutical equivalen comparative dissolution profile	ce and	Pharmaceutical Equivalence is established against the brand leader that is Maxum 2000mg injection batch No. 218006, mfg. date 02-2021 manufactured by M/s Highnoon pharma by performing quality tests (Identification, water content, pH, sterility, bacterial endotoxin & Assay).			
Analytical method validation/ve	erification of	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.			
	STABILIT	Y STUDY DA	ATA		
Manufacturer of API	Co., Ltd.,	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Ltd., West Side of yanbin Road, Feixian Economic Development, Shandong, China.			
API Lot No.	Not provide	ed.			
Description of Pack (Container closure system)	•	Transparent Type II glass vial filled with powder, closed with rubber stopper and flip-off seal.			
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 Accelerated				
Frequency		: 0, 3, 6 (Mon 0, 3, 6 (Montl			
Batch No.	TD	I001	TDI002	TCH001	
Batch Size					

Manufacturing Date 11-2			2021	11-2021	11-2021	
Date of Initiation 11-2			2021	11-2021	11-2021	
No. of	Batches			03		
REQUEST OF EXEMPTION FROM ON SITE INSPECTION						
The		equested for Exemption from On-site In lowing documents in conjunction with t				
		Adminis	trative P	ortion		
1.	Refere applica firm (i	ations with stability study data of the	The firm	has not submitted any	document.	
2.	API 1	val of API/ DML/GMP certificate of manufacturer issued by concerned tory authority of country of origin.	201505	as submitted copy of r 11 valid till 26-10-2025 aterials, Sterile raw mat		
3.		nents for the procurement of API with val from DRAP (in case of import).		Not sub	mitted.	
4.	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 1CFR & audit trail reports on product esting		Not Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Not Submitted			
Remar	ks by the E	· · · · · · · · · · · · · · · · · · ·	1			
Sr. No.	Section	Observations		Reply by the firm		
1.	1.5.2 or 3.2.P.5.1	Label claim of the applied formulation revised as per reference product with su of full fee.	bmission			
2.	1.5.5	Pharmacotherapeutic group shall be from third generation cephalosporin generation cephalosporin.				
3.	2.3.	Table for literature references shall be with inclusion of status of both drug stand finished product in pharmacopoeia.	substance			
4.	3.2.S.4.1	Specifications of the drug substance by substance manufacturer shall be submitted.	the drug			
5.	3.2.S.4.2	Analytical procedures for the drug substance used by the drug product manufacturer shall be submitted.				
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.				
7.	3.2.S.7	 Specifications of the drug substance by the drug substance manufact different from the specification of substance in the stability data Justification shall be submitted. Specifications of the drug substance in the drug substance in the drug substance in the drug substance in the drug substance in the drug substance in the drug substance in the drug substance in the drug substance in the drug substance in the drug substance in the drug substance in the drug substance in the drug substance in the drug substance in the drug substance in the drug substance in the stability data substance in the drug substance in the stability data substance	the drug sheets.			

		anhydrous and Arginine free basis" while the stability data sheets for the drug substance has	
		mentioned "NLT 83% of Cefepime calculated on anhydrous and Arginine free basis". Justification shall be submitted.	
8.	3.2.P.2.2	Justification shall be submitted for not performing PE against the innovator product.	
9.	3.2.P.5.2	Signed analytical procedures for the drug product shall be submitted.	
10.	3.2.P.8	 Identification test, water content tests are not performed in the stability studies of the drug product. Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number, date of initiation of stability studies and total batch size. Documents for the procurement of API with approval from DRAP shall be submitted. Reference of previous approval of applications with stability study data of the firm shall be submitted. Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. 	

Agenda of Evaluator PEC-XV

548.	Central Licensing Board in 272 nd meeting held on 17 th October,2019 has considered and approved additional section "Tablet II (General section)" of M/s Don Valley Pharmaceuticals Private Limited.			
	Name, address of Applicant / Marketing Authorization Holder	M/s Don Valley Pharmaceuticals Private Limited 31km Main Ferozepur Road Lahore		
	Name, address of Manufacturing site.	M/s Don Valley Pharmaceuticals Private Limited 31km Main Ferozepur 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)		
	Intended use of pharmaceutical product	☑ Domestic sale☐ Export sale☐ Domestic and Export sales		
	Dy. No. and date of submission	Dy. Nodated: 9th March 2023		
	Details of fee submitted	PKR 30,000/-: dated 09/02/2023		
	The proposed proprietary name / brand name	Ocalidon 5mg Tablet		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Obeticholic Acid5mg		
	Pharmaceutical form of applied drug	Yellow colored, Round biconvex shaped, without any score, Film coated oral tablet		
	Pharmacotherapeutic Group of (API)	Farnesoid X receptor agonists		
	Reference to Finished product	In-house		

	specifications		
	Proposed Pack size		3×10's
	Proposed unit price		As per SRO
			Ocaliva 5mg tablet by M/s Intercept Pharma Limited EMA Approved.
	For generic drugs (m	ne-too status)	Abeticholic 5mg Tablet by M/s Dyson Research Laboratories Pvt. Ltd., Reg. No. 109521
	GMP status of the Fi	inished product	Firm has submitted GMP certificate issued on dated 06-08-2019. Section approval letter issued on 05.11.2019
	Name and address of	f API manufacturer.	M/s Jari Pharmaceutical Co., Ltd. 18, Zhenhua Road, Lianyungang, Jiangsu Province China.
Module-II (Quality Overall Summary)		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		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 study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 24 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months Batches: (20171001, 20171101, 20171102)
	Module-III (Drug Pr	oduct):	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.
	comparative dissolution profile		Pharmaceutical Equivalence have been established against the innovator product that is Ocaliva 5mg tablet by Intercept Pharma International Limited, Ireland (Batch no. CE00024E) by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Ocaliva 5mg tablet by Intercept Pharma International Limited, Ireland (Batch no. CE00024E) in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
			Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
		STABILIT	TY STUDY DATA
Manufact	turer of API		l Co., Ltd. 18, Zhenhua Road, Lianyungang, Jiangsu Province
API Lot	No.	20220802	
Descripti	on of Pack	Alu-Alu blister packed	in unit carton (3×10's)

I					
(Contain	er closure syst	rem)			
Stability	Storage Cond	ition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}$			
Time Pe	riod	Real time: 3 months Accelerated: 3 months	S		
Frequen	су	Accelerated: 0, 3(Mor Real Time: 0, 3(Mont			
Batch N	0.	KB-22-001	KB-22-002	KB-22-003	
Batch Si	ze	5000 tab	5000 tab	5000 tab	
Manufac	cturing Date	10-2022	10-2022	10-2022	
Date of l	Initiation	28-10-2022	28-10-2022	28-10-2022	
No. of B	atches		03	,	
		Admir	nistrative Portion		
7.	applications firm (if any)	with stability study data of th	e Meeting	50 mg capsule approved in 324 DRB	
8.	API manufa	API/ DML/GMP certificate of acturer issued by concerned thority of country of origin.		o. JS20191190 issued by Jiangsu till 29/11/2024.	
9.		or the procurement of API with DRAP (in case of import).	 Copy of letter No. K-1107632926281 dated 13/10/2022 is submitted wherein the permission to import different APIs including Obeticholic Acid for the purpose of test/analysis and stability studies is granted. Invoice No. 22YX0049L dated 15/09/2022 		
10.	attested re	ity batches will be supported by espective documents likens, Raw data sheets, COA a sheets etc.	e	Submitted	
11.		Record of HPLC software audit trail reports on produc		Submitted	
12.	and humidi	gital data logger for temperatur ity monitoring of stability al time and accelerated)		Submitted	
	s OF Evaluat				
S.no. 1.	Sections 3.2. S.4.1	Justify for not including the te	of drug substance by drug	n, palladium test and solid state substance manufacturer, since	
2.	3.2.S.4.1- 3.2.S.4.2	 Submit copies of the Drug routine testing of the Drug product manufacturer as which specifies that "Coprocedures used for rout Ingredient by both Drug you have only submitted manufacturer. Submit detailed analytimanufacturer, since the 	submit detailed analytical procedure of drug substance by drug substance nanufacturer, since the submitted procedure seems incomplete or only refer the		
3.	3.2.S.4.3	Justify for performing val	eneral chapters of USP. ustify for performing validation study of assay procedure which is different from the ssay method by drug substance manufacturer given in section 3.2.S.4.2.		

		• Further drug substance manufacturer used RID detector in the HPLC system for assay while the submitted chromatogram of validation studies reflect that the assay has performed by setting the wavelength of detector at 210nm, Justify for using the different detector from that specified by drug substance manufacturer.		
4.	3.2.S.5	COA of primary/secondary reference standard including source and lot no. is required.		
5.	3.2.S.7	According to the review literature of innovator brand storage condition of drug substance is 5°C±3°C with the retest period of 36months then justify the testing condition of given stability data of drug substance i.e. 30±2°C RH 65±5% & 40±2°C RH 75±5%.		
6.	3.2.P.2.2.1	 Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution mediums while referring to the innovator drug product literature wherein the drug substances have been reported as BCS Class II drug substances and the recommended dissolution medium contains surfactant polysorbate 80. In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed. 		
7.	3.2.P.5.2	preparation of standard soluti performing the assay and disso		
8.	3.2.P.5.3	Justify for not performing the validation study on the same assay procedure which is given in section 3.2.P.5.2, specifically with reference to the preparation of both standard and sample preparation. Further, analytical method validation reports reflects that the assay procedure which has been validated is different from assay procedure given in section 3.2.P.5.2 and also not similar to the method specified in AMV protocol.		
9.	3.2.P.5.4	• •	content uniformity test while finished product analysis of included in the specification of finished drug product.	
10.	3.2.P.8	 month stability data. Submit documents for the attested by AD (I&E) DRA 	MP certificate of API manufacturer issued by concerned	
11.	2.3.R.1.1		ater content in the dispensing weight of API since the assay rous as evident from the COA of API.	
Decision	: Registratio	n Board deferred the case for	submission of reply to the above cited shortcomings.	
549.	Name, addre Authorizatio	ss of Applicant / Marketing n Holder	M/s Don Valley Pharmaceuticals Private Limited 31km Main Ferozepur Road Lahore	
	Name, addre	ess of Manufacturing site.	M/s Don Valley Pharmaceuticals Private Limited 31km Main Ferozepur Road Lahore	
	Status of the	applicant	 ✓ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver) 	
	Status of app	olication	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product		☑ Domestic sale☐ Export sale☐ Domestic and Export sales	
	Dy. No. and	date of submission	Dy. No6676 dated: 9th March 2023	
	Details of fe	e submitted	PKR 30,000/-: dated 09/02/2023	
	The propose name	d proprietary name / brand	Ocalidon 10mg Tablet	

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Obeticholic Acid10mg
Pharmaceutical form of applied drug	Red colored, Round biconvex shaped, without any score, Film coated oral tablet
Pharmacotherapeutic Group of (API)	Farnesoid X receptor agonists
Reference to Finished product specifications	In-house
Proposed Pack size	3×10's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Ocaliva 10mg tablet by M/s Intercept Pharma Limited EMA Approved.
For generic drugs (me-too status)	Abeticholic 10mg Tablet by M/s Dyson Research Laboratories Pvt. Ltd., Reg. No. 109522
GMP status of the Finished product manufacturer	Firm has submitted GMP certificate issued on dated 06-08-2019. Section approval letter issued on 05.11.2019
Name and address of API manufacturer.	M/s Jari Pharmaceutical Co., Ltd. 18, Zhenhua Road, Lianyungang, 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, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 24 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months Batches: (20171001, 20171101, 20171102)
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Brand Leader that is Ocaliva 10mg tablet by Intercept Pharma International Limited, Ireland (Batch no. CE00024E) by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Ocaliva 10mg tablet by Intercept Pharma International Limited, Ireland (Batch no. CE00024E) in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
Analytical method validation/verification of	Method validation studies have submitted including linearity,

	product		range accur	acy, precision, specifici	fv
		-		.y.	
Manufas	Manufacturer of API M/s Jari Pharmaceutical Co., Ltd. 18, Zhenhua Road, Lianyungang, Jiangsu Provin				
Manurac	turer of API	China.	M/s Jari Pharmaceutical Co., Ltd. 18, Zhenhua Road, Lianyungang, Jiangsu Province		
API Lot	No.	20220802			
	ion of Pack er closure sys	Alu-Alu blister p	acked in unit carton	(3×10's)	
Stability	Storage Cond		$\pm 2^{\circ}$ C / 65% ± 5 % RFC $\pm 2^{\circ}$ C / 75% ± 5 %		
Time Pe	riod	Real time: 6 mor Accelerated: 6 m			
Frequen	су	Accelerated: 0, 3 Real Time: 0, 3,			
Batch N	0.	KA-22-001	KA-22-002	KA-22-	003
Batch Si	ze	5000 tab	5000 tab	5000 tal	b
Manufac	turing Date	10-2022	10-2022	10-2022	2
	Initiation	28-10-2022	28-10-2022	28-10-2	022
No. of B	atches			03	
		A	dministrative Port	ion	
1.	Reference of previous approval of applications with stability study data of the firm (if any) Gutain 30 mg and Gutain 60 mg capsule approved in 324 D Meeting				
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Copy of GMP certificate No. JS20191190 issued by Jian Drug Administration valid till 29/11/2024.				
3.	Documents for the procurement of API with approval from DRAP (in case of import).		rt). submitted including and stabili	 Copy of letter No. K-1107632926281 dated 13/10/2022 is submitted wherein the permission to import different APIs including Obeticholic Acid for the purpose of test/analysis and stability studies is granted. Invoice No. 22YX0049L dated 15/09/2022 	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		like	Submitted	i
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	1
Remark	s OF Evaluat	or:	·		
S.no.	Sections			encies/ Short-comings	
1.	3.2. S.4.1	Justify for not including form test in the specific	cation of drug subst	ance by drug substance	e manufacturer, since
2.	 these tests are included in the spe 3.2.S.4.1- Submit copies of the Drug submit copies of the D		e Drug substance spe e Drug substance /A	cifications and analyticative Pharmaceutical I	al procedures used for ngredient by the drug

3.	3.2.S.4.3	procedures used for routing Ingredient by both Drug suryou have only submitted the manufacturer. Submit detailed analytic manufacturer, since the submit general chapters of USP. Justify for performing valid	pies of the Drug substance specifications and analytical ne testing of the Drug substance /Active Pharmaceutical substance & Drug Product manufacturer is required". Since he specification and analytical procedure by drug substance all procedure of drug substance by drug substance submitted procedure seems incomplete or only refer the dation study of assay procedure which is different from the stance manufacturer given in section 3.2.S.4.2.		
		Further drug substance may while the submitted chror performed by setting the different detector from that	nufacturer used RID detector in the HPLC system for assay matogram of validation studies reflect that the assay has wavelength of detector at 210nm, Justify for using the t specified by drug substance manufacturer.		
4.	3.2.S.5	COA of primary/secondary ref	Gerence standard including source and lot no. is required.		
5.	3.2.S.7	is 5°C±3°C with the retest per	ture of innovator brand storage condition of drug substance iod of 36months then justify the testing condition of given e i.e. 30±2°C RH 65±5% & 40±2°C RH 75±5%.		
6.	3.2.P.2.2.1	 Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution mediums while referring to the innovator drug product literature wherein the drug substances have been reported as BCS Class II drug substances and the recommended dissolution medium contains surfactant polysorbate 80. In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies 			
7.	3.2.P.5.2	have been performed. Clarification is required for not using reference standard/working standard for the preparation of standard solution as reflects from the given analytical procedures while performing the assay and dissolution of drug product.			
8.	3.2.P.5.3	Justify for not performing the validation study on the same assay procedure which is given in section 3.2.P.5.2, specifically with reference to the preparation of both standard and sample preparation. Further, analytical method validation reports reflects that the assay procedure which has been validated is different from assay procedure given in section			
9.	3.2.P.5.4	Justify for not performing the	3.2.P.5.2 and also not similar to the method specified in AMV protocol. Justify for not performing the content uniformity test while finished product analysis of drug product, since the test is included in the specification of finished drug product.		
10.	3.2.P.8	 Submit the updated stability data of drug product, since you have submitted only three-month stability data. Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. 			
11.	2.3.R.1.1	Justify for not adjusting the wa	nter content in the dispensing weight of API since the assay ous as evident from the COA of API.		
Decision	: Registration	n Board deferred the case for s	submission of reply to the above cited shortcomings.		
550.	Oral liquid s	yrup section (general) is approve	ed vide letter No. F. 1-25/2008-Lic dated 17-09-		
	Name, addre Authorizatio	ess of Applicant / Marketing n Holder	M/s. World Biz Pharmaceutical Company Plot No. 340, Multan Industrial Estate, Multan.		
	Name, addre	ess of Manufacturing site.	M/S World Biz Pharmaceutical Company Plot No. 340, Multan Industrial Estate, Multan.		
	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.706 : dated 09-01-2023.	
Details of fee submitted	PKR 30,000/- vide slip No. 67913763 dated 03-01-2023.	
The proposed proprietary name / brand name	SetBiz 5mg/5ml syrup.	
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Cetirizine dihydrochloride 5mg (B.P Specifications)	
Pharmaceutical form of applied drug	Oral liquid.	
Pharmacotherapeutic Group of (API)	R06AE07 Antihistamine	
Reference to Finished product specifications	BP Specification	
Proposed Pack size	60ml,90ml,120ml,450ml	
Proposed unit price	As per SRO	
The status in reference regulatory authorities	USFDA APPROVED	
For generic drugs (me-too status)	Citzin Syrup, NovaMed Pharmaceuticals, Reg. No. 063620.	
GMP status of the Finished product manufacturer	New license issued dated 14-09-2021 w.e.f. 13-09-2021.	
Name and address of API manufacturer.	Oral liquid syrup section (general) is approved vide letter No. F. 1-25/2008-Lic dated 17-09-2021.	
Module-II (Quality Overall Summary)	M/s Sreekara Organics India Plot No. 159/A, S.V. Co-op. Ind. Estate, IDA Bollaram, Jinnaram (M), Sangareddy Dist-502325, Telangana, India.	
Module III (Drug Substance)	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.	
Stability studies	Official monograph of Cetirizine Hydrochloride is present in B.P. Firm has submitted detail of nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurities & 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-III (Drug Pr	roduct):	Firm has submitted stability	tv study data of 3	
	Triodule III (Brug I I	i oddetji	batches of drug substance at both accelerated as		
			well as real time condition		
			The accelerated stability da ± 5% RH for 6 months.	ata is conducted at $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\%$	
				a is conducted at $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65 \pm$	
			5% RH for 60 months.		
	DI		Batches:(CZ/V/00411,CZ/		
	comparative dissolution profile		manufacturing process and analytical procedure (include buffer medium) and its ver	tail of manufacturers, description of controls, impurities, specifications, ding dissolution testing at acidic and ification studies, batch analysis and ion, reference standard, container y studies of drug product.	
			Pharmaceutical Equivalence	ce is established against the Citzin	
	product		• •	NovaMed pharmaceuticals Lahore	
			by performing quality tests (Identification, filled volume, leakage teat, pH and Assay). Results of both the products are		
			similar.	y). Results of som the products are	
			CDP is not applicable.		
		1	TY STUDY DATA		
Manufac	cturer of API	I — —	M/s Sreekara Organics India Plot No. 159/A, S.V. Co-op. Ind. Estate, DA Bollaram, Jinnaram (M), Sangareddy Dist-502325, Telangana, India.		
API Lot	No.	CTZ03521			
	ion of Pack ner closure system)	An amber glass bottle containing an-off white colored syrupy liquid with pleasant flavour, sealed with aluminum pp cap and packed in specific unitcarton.			
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time Period		Real time: 6 months Accelerated: 6 months			
Frequency		Accelerated: 0, 3, 6 (Mo Real Time: 0, 3, 6 (Mor			
Batch No	0.	RD-CS-001	RD-CS-001	RD-CS-001	
Batch Si	ze	500 bottles.	500 bottles.	500 bottles.	
Manufac	cturing Date	09-2022	09-2022	09-2022	
Date of l	Initiation	28-09-2022.	28-09-2022.	28-09-2022.	
No. of B	atches	03			
		Admini	strative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)			py of approval of PolyBiz syrup in	
2.	Approval of API/ DML/GMP certificate of			on Government of Telangana issued	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		material of quantity 500	Og was obtained via loan from Lahore. Copy of documents	

				• Copy of Form 3, 5 ,7 from & invoice (invoice# ZHI-CI/5465/0621) dated: 26-06-2021 cleared by DRAP Lahore office dated 12-07-2021 specifying import 100Kg Cetirizine 2HCl(Batch# CTZ03521)	
4.	attes	chromatograms, Raw data sheets, COA, summary data sheets		supported by attested respective documents like chromatograms, raw data sheets, COA, summary	
5.	21Cl	Compliance Record of HPLC software 21CFR & audit trail reports on product testing			
6.	and	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	
Rema	rks OF	Evaluat	or:		
S.nc		ctions		ations/Deficiencies/ Short-comings	
	1. 3.2.5	S.7		test of pH determination and loss on drying test while	
	2. 3.2.]	P.1	performing the stability studies Formulation contain preservati	ive, so preservative effectiveness studies to be performed as	
			per recommendations of pharn		
3					
	4. 3.2.				
-	5. 3.2.1	P.5.2			
(Submit the updated stability data of drug product, since you have submitted only three-month stability data. Approval of API/ DML/ valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. 				
Decis	ion: Reg	gistration	n Board deferred the case for s	submission of reply to the above cited shortcomings.	
551.	51. Central Licensing Board in 278 th meeting held on 10 th &11 th December,2020 has considered and ap additional section "Liquid Ampoule (SVP) General Section" of M/s Islam Pharmaceuticals, Sialkot.				
Name, address of Applicant / I Authorization Holder		11	M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot		
	Name, address of Manufacturing site. Status of the applicant		of Manufacturing site.	M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot	
			blicant	 ✓ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver) 	
	Status o	atus of application		☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)	
	Intende	d use of	pharmaceutical product	☑ Domestic sale	

	☐ Export sale ☐ Domestic and Export sales	
Dy. No. and date of submission	Dy. No. 22726 Dated: 11/08/2022 PKR 30,000/- Dated: 02/12/2021 Diflo 75mg/3ml Injection	
Details of fee submitted		
The proposed proprietary name / brand name		
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 3ml ampoule contains: Diclofenac Sodium75mg	
Pharmaceutical form of applied drug	Clear and colorless solution filled in clear glass ampoules	
Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)	
Reference to Finished product specifications	Innovator	
Proposed Pack size	3ml×10'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 by Asian Continental (Pvt.) Ltd. Reg. No. 007737	
GMP status of the Finished product manufacturer	New Section for liquid ampoule (SVP) General was granterafter inspection vide letter No. F. 1-19/2014-Lic (Vol-1) Dated: 18/12/2020	
Name and address of API manufacturer.	Shaanxi Xiyue Pharmaceutical Co., Ltd. Huashan town, huayi city, veinan city, shaanxi province 714200, 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, bate 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)	Diclofenac sodium is as per USP Specifications. The firm a submitted detail of nomenclature, structure, general properties solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substance by HPLC (any individual impurity and Total Impurities specifications, analytical procedures and its verification, bate analysis and justification of specification, reference standard container closure system and stability studies of dru substance.	
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 06 months Batches:(1702201,1702202, 1702203)	
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specification analytical procedure and its validation studies, batch analyst and justification of specification, reference standard, contained closure system and stability studies of drug product.	
Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator product that is Voren injection 750mg/3n injection by Asian Continental Pvt. Ltd. by performing quality	

1	. 3.2.S.4.4	Justify for not importing/using results of sterility test and Ra	_	nufacturing of injection, since the		
S.no			ations/Deficiencies/ Sho			
	rks OF Evaluato					
6.		al data logger for temperature onitoring of stability chambers celerated)				
	& audit trail repo	ord of HPLC software 21CFR orts on product testing	Submitted			
	attested respective chromatograms, Raw data sheets,	batches will be supported by ective documents like COA, summary data sheets etc.	Submitted			
	Documents for the procurement of API with approval from DRAP (in case of import).		16/10/2020 is submit different APIs included of test/analysis and s • AirWay Bill No.6071 Dated 22/12/2020	4850/2020/DRAP-AD-VIII (I&E) dated itted wherein the permission to import ding Diclofenac sodium for the purpose tability studies is granted. PVG91267326		
	manufacturer iss authority of coun	sued by concerned regulatory try of origin.	valid till 24/02/2024.	ate No. SN20190340 issued by CFDA		
		vious approval of applications dy data of the firm (if any)	The firm has not submi (New Section)	tted any document.		
Admi	nistrative Portio	n				
No. of	Batches	03	1	<u>'</u>		
	of Initiation	24-05-2021	24-05-2021	24-05-2021		
	facturing Date	04-2021	04-2021	04-2021		
Batch		2000 ampoules	2000 ampoules	2000 ampoules		
Freque Batch		Accelerated: 0, 3, 6 (Mor Real Time: 0, 3, 6 (Mor 21ARn048		21ARn050		
	Period	Accelerated: 03 months	Real time: 03 months Accelerated: 03 months			
	ity Storage Condi	Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$			
Descri	iption of Pack ainer closure syste	LISD Type I Clear Glass	USP Type-I Clear Glass ampoules in PVC Tray, packed in unit carton (3ml×10's)			
API Lot No.		2010205	province 714200, china.			
	facturer of API	Shaanxi Xiyue Pharmac		n town, huayin city, veinan city, shaanx		
STAB	STABILITY STUDY DATA		Linearity, Range, Accu	racy, Precision, Robustness.		
-	Analytical meth	nod validation/verification of	Method validation studies have submitted including Specificity, Limit of Detection, Limit of Quantitation			
			Variation).	entification, Assay, pH and Volumerare in the acceptable range.		

results of sterility test and Bacterial Endotoxin test is not included in the COA of drug

substance by both drug substance manufacturer and drug product manufacturer.

2.	3.2.P.1	• Clarify the role of benzyl alcohol in the applied formulation.		
		• According to the literature of innovator brand the recommended quantity of Sodium		
		metabisulphite is 2 mg per 3 ml and Benzyl alcohol is 120 mg per 3 ml, while the		
		quantity of both excipients used in the applied formulation is different from the		
		recommended quantity by the innovator, scientifically rationalize the quantity of both		
		excipients used in the applied formulation.		
3.	3.2.P.2.2.1	1 Justify for not performing the test of osmolality, particulate matter, sterility and Bacterial		
		Endotoxin test while establishing the pharmaceutical equivalence against the reference		
		product.		
4.	3.2.P.3.3	Justify for preferring the aseptic filling procedure over terminal sterilization in the		
		manufacturing procedure of drug product.		
5.	3.2.P.5.1	Submit reference of specification of pH test.		
		• Justify for not including the test of osmolality in the finished product specification since		
		it is the critical parameter in the injectable formulation.		
6.	<u> </u>			
		month stability data.		
		Clarify the volume of glass ampoule use for primary packaging of drug product, since		
		it is mentioned 1ml on stability data sheet while the applied formulation is of 3ml.		
7.	2.3.R.1.1			
		batches.		

Agenda of Evaluator PEC-XX

Case No. 00 Registration applications of newly granted DML or New section (Human)

New License

M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat. The Central Licensing Board in its 285th meeting held on 17th & 18th March, 2022 has considered and approved the grant of Drug Manufacturing License to M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat by way of Formulation vide approval letter No. F. 1-8/2019-Lic dated 29th April, 2022 with following (03) sections:

S No.	Section	
1	Tablet (General) section	
2	Capsule (General) section	
3	Cream/ointment (General) section	

1.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Status of the applicant	 ☑Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	 □ Domestic sale □ Export sale ☑ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4379 dated 15/02/2023

Details of fee submitted	PKR 30,000/- dated 06/02/2023
The proposed proprietary name / brand name	Q-Pine 25mg tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Quetiapine (as fumarate)25mg
Pharmaceutical form of applied drug	Tablet
Pharmacotherapeutic Group of (API)	Psycholeptic, <u>Diazepines</u> , <u>oxazepines</u> , <u>thiazepines</u> ar <u>oxepines</u>
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)	Evokalm Tablet by M/s Pharmevo, Karachi Reg. No. 039621
GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285 th meeti of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
Name and address of API (pellets) manufacturer.	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templa Summarized information related to nomenclature, structure general properties, Solubility, physical form, manufacture description of manufacturing process and controls, impurities specifications, analytical procedures and its verification, bat analysis and justification of specification, reference standar container closure system and stability studies of drug substant and drug product is submitted.
Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure general properties, solubility, physical form, manufacture description of manufacturing process and control specifications, analytical procedures and its verification, bat analysis and justification of specification, reference standard container closure system and stability studies of drug substantial
Stability studies	Stability study conditions: Real time: $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$ RH for 12 months Accelerated: $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%$ RH for 6 months Batches: QTP/II/V/026/14-15, QTP/II/V/027/14-15, QTP/II/V/028/115,
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description manufacturing process and controls, specifications, analytic procedure and its verification studies, batch analysis a justification of specification, reference standard, contain closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against treference product that is Seroquel tablet 25mg Batch 14983763 by ICI Pakistan Ltd, by performing quality te (Identification, Assay, Dissolution, Uniformity of dosage for and weight Variation and DT) against Test Product Q-Pi

		25mg tablet Batch No Q00	1.	
		CDP has been performed against the same brand that Seroquel tablet 25mg in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.		
Analytical method vaproduct	alidation/verification of	Method verification stud accuracy, precision, specific	dies have submitted including city and system suitability.	
	STABILIT	TY STUDY DATA		
Manufacturer of API (pellets)	M/s Laksh Finechem (P Udyognagar, Anand, Gu	vt) Ltd Plot No. 1801/02, Ph ıjrat India	ase –IV G.I.D.C Vitthal	
API Lot No.	LF-QUEF/112020/013			
Description of Pack (Container closure system)	Alu-Alu blister			
Stability Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 4$ 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 (Mon	•		
Batch No.	Q001	Q002	Q003	
Batch Size	1500 tablet	1500 tablet	1500 tablet	
Manufacturing Date	05-2022	05-2022	05-2022	
Date of Initiation	07-05-2022	09-05-2022	10-05-2022	
No. of Batches		03		
Adminis		strative Portion		
1. Reference of previous with stability study dat	approval of applications a of the firm (if any)	Nil		
2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.				
3. I Documents for the procurement of API with approval from DRAP (in case of import).		dated 04-12-2020 for impo (Batch No LF-QUEF/112 Panacea pharmaceuticals Is	of invoice No. ZHI-CI/5073/1220 rt of 55Kg of Quetiapine fumarate 020/013) wherein name of M/s lamabad, Pakistan was mentioned, P Islamabad dated 31-12-2020.	
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Submitte	ed	
5. Compliance Record of & audit trail reports on	HPLC software 21CFR product testing	Not provided		
and humidity monitori				

- **1.6.5** Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- **3.2.S.4** Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
- **3.2.P.2.1.1** Compatibility of the Drug Substance(s) with excipients (Talc and IPA) is not provided. Since said ingredients are not found in innovator's formulation.
- **3.2.P.2** Parameters like Linearity and Range are not performed under product Analytical method verification study
- **3.2.P.2** Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study
- **3.2.P.8** Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020. Clarify it
- **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided

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

ion. Registration board deferred the east for	submission of Tepry to the above cited shortcomings.
Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
Status of the applicant	 ☑Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)
Intended use of pharmaceutical product	 □ Domestic sale □ Export sale ☑ Domestic and Export sales
Dy. No. and date of submission	Dy. No. 4378 dated 15/02/2023
Details of fee submitted	PKR 30,000/- dated 06/02/2023
The proposed proprietary name / brand name	Q-Pine 100mg tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Quetiapine (as fumarate)100mg
Pharmaceutical form of applied drug	Tablet
Pharmacotherapeutic Group of (API)	Psycholeptic, <u>Diazepines</u> , <u>oxazepines</u> , <u>thiazepines</u> and <u>oxepines</u>
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)	Evokalm Tablet by M/s Pharmevo, Karachi Reg. No. 042222
GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285 th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section

	Cream/ointment (General) section
of API (pellets)	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India
erall 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.
cance)	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
	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 6 months Batches: QTP/II/V/026/14-15, QTP/II/V/027/14-15, QTP/II/V/028/14-15,
uct):	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.
lence and comparative	Pharmaceutical Equivalence have been established against the reference product that is Seroquel tablet 100mg by ICI Pakistan Ltd, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation and DT) against Test Product Q-Pine 100mg tablet CDP has been performed against the same brand that Seroquel tablet 100mg in Acid media (pH 1.0-1.2), Acetate
1:1.:. / :5:	Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Method verification studies have submitted including accuracy, precision, specificity and system suitability.
	TY STUDY DATA
Udyognagar, Anand, Gu	vt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal ijrat India
LF-QUEF/112020/013	
Alu-Alu blister	
Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 6$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$	
Real time: 6 months Accelerated: 6 months	
Accelerated: 0, 3,6 (Mor Real Time: 0, 3,6 (Mon	·
	erall Summary) tance) uct): lence and comparative STABILIT M/s Laksh Finechem (P Udyognagar, Anand, Gu LF-QUEF/112020/013 Alu-Alu blister Real time: 30°C ± 2°C / Accelerated: 40°C ± 2°C Real time: 6 months Accelerated: 0, 3,6 (Months)

Batc	h No.	Q004	Q005	Q006
Batc	h Size	1500 tablet	1500 tablet	1500 tablet
Man	ufacturing Date	05-2022	05-2022	05-2022
Date	of Initiation	07-05-2022	09-05-2022	10-05-2022
No. o	of Batches		03	
		Admini	strative Portion	
1.	Reference of previous with stability study dat	approval of applications a of the firm (if any)		Nil
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		A •	2046 dated 16.05.2014 valid till and Drug Administration ,Gujrat
3.	3. I Documents for the procurement of API with approval from DRAP (in case of import).		dated 04-12-2020 for impo (Batch No LF-QUEF/112 Panacea pharmaceuticals Is	of invoice No. ZHI-CI/5073/1220 ort of 55Kg of Quetiapine fumarate 2020/013) wherein name of M/s slamabad, Pakistan was mentioned, P Islamabad dated 31-12-2020.
4.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			No Q005 and Q006 were not
5.	5. Compliance Record of HPLC software 21CFR & audit trail reports on product testing		No	ot provided
6.	6. Record of Digital data logger for temperature and humidity monitoring of stability chambers			ubmitted

(real time and accelerated) Remarks of Assessor (DD PEC XX):

- **1.6.5** Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- **3.2.S.4** Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
- **3.2.P.2.1.1** Compatibility of the Drug Substance(s) with excipients (Talc and IPA) is not Provided. Since said ingredient is not found in innovator's formulation.
- **3.2.P.2** Parameters like Linearity and Range are not performed under product Analytical method verification study
- **3.2.P.2** Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study
- **3.2.P.2** Brand names of innovator and Test product used in Pharmaceutical equivalence study/CDP, to be provided
- **3.2.P.8** Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020. Clarify it.
- 3.2.P.8 Chromatograms for Batch No Q005 and Q006 to be submitted against each time point.
- **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided

Decision: Registration Board deterred the case for submission of reply to the above cited shortcomings.		
3.	Name, address of Applicant / Marketing	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI,
	Authorization Holder	Industrial estate. Rawat.

Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RC0 Industrial estate. Rawat.
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. 4617 dated 17/02/2023
Details of fee submitted	PKR 30,000/- dated 06/02/2023
The proposed proprietary name / brand name	Q-Pine 200mg tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Quetiapine (as fumarate)200mg
Pharmaceutical form of applied drug	Tablet
Pharmacotherapeutic Group of (API)	Psycholeptic, <u>Diazepines</u> , <u>oxazepines</u> , <u>thiazepines</u> a <u>oxepines</u>
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)	Evokalm Tablet by M/s Pharmevo, Karachi Reg. No. 053199
GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285 th meet of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
Name and address of API (pellets) manufacturer.	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templa Summarized information related to nomenclature, structure general properties, Solubility, physical form, manufactured description of manufacturing process and controls, impuriting specifications, analytical procedures and its verification, based analysis and justification of specification, reference standar container closure system and stability studies of drug substantian drug product is submitted.
Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure general properties, solubility, physical form, manufacture description of manufacturing process and control specifications, analytical procedures and its verification, based analysis and justification of specification, reference standard container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug substantial container closure system and stability studies of drug system and stability studies of drug system and stability studies of drug system and sta
Stability studies	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 12 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months

			lamabad, Pakistan was mentioned, P Islamabad dated 31-12-2020.	
3. Documents for the procurement of API with approval from DRAP (in case of import).		dated 04-12-2020 for impor	of invoice No. ZHI-CI/5073/1220 rt of 55Kg of Quetiapine fumarate 020/013) wherein name of M/s	
2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		A *		
1.	Reference of previous with stability study dat	approval of applications a of the firm (if any)		Nil
		Admini	strative Portion	
No. o	of Batches		03	
Date	of Initiation	07-05-2022	09-05-2022	10-05-2022
Man	ufacturing Date	05-2022	05-2022	05-2022
	h Size	1500 tablet	1500 tablet	1500 tablet
	h No.	Real Time: 0, 3,6 (Mon	,	Q009
Time Period Real time: 6 months Accelerated: 6 months Frequency Accelerated: 0, 3,6 (Mo		nths)		
Stability Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$				
(Con	ription of Pack tainer closure system)	Alu-Alu blister		
API	Lot No.	LF-QUEF/112020/013		
(pelle		Udyognagar, Anand, Gu	•	ase -1 v O.1.D.C v Ittildi
Man	ufacturer of API		TY STUDY DATA vt) Ltd Plot No. 1801/02, Ph	ase _IV G I D C Vitthal
	Analytical method vaproduct		accuracy, precision, specific	dies have submitted including city and system suitability.
			CDP has been performed against the same brand that Evokalm tablet 200mg in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.	
	Pharmaceutical equivalence and comparative dissolution profile		reference product that is Pharmevo, Karachi by perfo Assay, Dissolution, Unifor	e have been established against the Evokalm tablet 200mg by M/s orming quality tests (Identification, mity of dosage form and weight Test Product Q-Pine 200mg tablet
			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.	
			Batches: QTP/II/V/026/14-15, QTP/ 15,	II/V/027/14-15, QTP/II/V/028/14-

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)	Submitted	

- **1.6.5** Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- **3.2.S.4** Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
- **3.2.P.2.1.1** Compatibility of the Drug Substance(s) with excipients (Talc and IPA) is not Provided. Since said ingredients are not found in innovator's formulation.
- **3.2.P.2** Parameters like Linearity and Range are not performed under product Analytical method verification study
- **3.2.P.2** Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study
- **3.2.P.2** Brand names of innovator and Test product used in Pharmaceutical equivalence study/CDP, to be provided. Also justify selection of said brand instead of innovator.
- **3.2.P.8** Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020. Clarify it.
- **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings. M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4, RCCI, Name, address of Applicant / Marketing Authorization Holder Industrial estate. Rawat. M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4..RCCI. Name, address of Manufacturing site. Industrial estate, Rawat, 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 Dy. No. and date of submission Dy. No. 4618 dated 17/02/2023 Details of fee submitted PKR 30,000/- dated 06/02/2023 The proposed proprietary name / brand name Q-Pine 300mg tablet Strength / concentration of drug of Active Each film coated tablet contains: -Pharmaceutical ingredient (API) per unit Quetiapine (as fumarate)...300mg Pharmaceutical form of applied drug Tablet

Pharmacotherapeutic Group of (API)	Psycholeptic, <u>Diazepines</u> , <u>oxazepines</u> , <u>thiazepines</u> <u>oxepines</u>
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)	Rekyt Tablet by M/s High Q, Karachi Reg. No. 112752
GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285 th mee of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
Name and address of API (pellets) manufacturer.	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –l G.I.D.C Vitthal Udyognagar, Anand, Gujrat India
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD temporal summarized information related to nomenclature, struct general properties, Solubility, physical form, manufacturing description of manufacturing process and controls, impuris specifications, analytical procedures and its verification, be analysis and justification of specification, reference stand container closure system and stability studies of drug substant drug product is submitted.
Module III (Drug Substance)	The firm has submitted detail of nomenclature, struct general properties, solubility, physical form, manufacturidescription of manufacturing process and contispecifications, analytical procedures and its verification, be analysis and justification of specification, reference stand container closure system and stability studies of drug substations.
Stability studies	Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 12 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%\text{RH}$ for 6 months Batches: QTP/II/V/026/14-15, QTP/II/V/027/14-15, QTP/II/V/028 15,
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description manufacturing process and controls, specifications, analyst procedure and its verification studies, batch analysis justification of specification, reference standard, contactors closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against reference product that is Evokalm tablet 300mg by Pharmevo, Karachi by performing quality tests (Identificat Assay, Dissolution, Uniformity of dosage form and we Variation and DT) against Test Product Q-Pine 300mg ta
	CDP has been performed against the same brand that Evokalm tablet 300mg in Acid media (pH 1.0-1.2), Aceta Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The value for f1 and f2 are in the acceptable range.
Analytical method validation/verification of product	Method verification studies have submitted incluaccuracy, precision, specificity and system suitability.

		STABILI	ΓΥ STUDY DATA	
Manu (pelle		M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India		
API I	Lot No.	LF-QUEF/112020/013		
	ription of Pack tainer closure system)	Alu-Alu blister		
Stabi	lity Storage Condition	Real time: 30°C ± 2°C / Accelerated: 40°C ± 2°C		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequ	iency	Accelerated: 0, 3,6 (Mo Real Time: 0, 3,6 (Mor	•	
Batch	ı No.	Q010	Q011	Q012
Batch	n Size	1500 tablet	1500 tablet	1500 tablet
Manu	facturing Date	05-2022	05-2022	05-2022
Date	of Initiation	07-05-2022	09-05-2022	10-05-2022
No. o	of Batches		03	
		Admini	strative Portion	
1.	Reference of previous with stability study dat	approval of applications ta of the firm (if any)		Nil
2.	2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory		A •	/2046 dated 16.05.2014 valid till d and Drug Administration ,Gujrat
3. I	3. I Documents for the procurement of API with approval from DRAP (in case of import).		dated 04-12-2020 for impo (Batch No LF-QUEF/11: Panacea pharmaceuticals I	of invoice No. ZHI-CI/5073/1220 ort of 55Kg of Quetiapine fumarate 2020/013) wherein name of M/s slamabad, Pakistan was mentioned, AP Islamabad dated 31-12-2020.
4.	4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		CoA Raw data sheet and were not submitted	Chromatograms for Batch No Q012
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		No	ot provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)			Submitted
Dame	owks of Assessor (DD D	DEC XX		

- **1.6.5** Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- **3.2.S.4** Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
- **3.2.P.2.1.1** Compatibility of the Drug Substance(s) with excipients (Talc and IPA) is not Provided. Since said ingredients are not found in innovator's formulation.
- **3.2.P.2** Parameters like Linearity and Range are not performed under product Analytical method verification study
- **3.2.P.2** Results of specificity parameter along with HPLC chromatograms (sample, standard,

- placebo and blank) has not been provided under product Analytical method verification study
- **3.2.P.2** Brand names of innovator and Test product used in Pharmaceutical equivalence study/CDP, to be provided. Moreover, registration status of Evokalm tablet 300mg to be provided.
- **3.2.P.8** Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020. Clarify it.
- **3.2.P.8** CoA Raw data sheet and Chromatograms for Batch No Q012 were not submitted against each time point.
- **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided

be provided	
	submission of reply to the above cited shortcomings.
Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.
Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot#40, Street#S-6,National Industrial Zone, Raw 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
Dy. No. and date of submission	Dy. No. 4615 dated 17/02/2023
Details of fee submitted	PKR 30,000/- dated 06/02/2023
The proposed proprietary name / brand name	Deslor 5mg tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Desloratadine5mg
Pharmaceutical form of applied drug	Film coated tablet
Pharmacotherapeutic Group of (API)	Antihistamines
Reference to Finished product specifications	USP
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Clarinex 5mg tablet by M/s Schering-Plough USFI approved
For generic drugs (me-too status)	Larinex 5mg Tablet by M/s Getz Pharma Pakistan, Reg. N 039175
GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285 th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
Name and address of API manufacturer.	M/s Smaart Pharmaceuticals Limited. B-22/23, MIDC, Ajanta Road, Jalgaon Maharashtra (India) - 425 003.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD templa Summarized information related to nomenclature, structu

			description of manufacturing specifications, analytical pranalysis and justification of	ities, physical form, manufacturers, ng process and controls, impurities, rocedures and its verification, batch of specification, reference standard, nd stability studies of drug substance ted.
			firm has submitted detail properties, solubility, description of manufactur impurity, specifications, verification, batch analysis	sloratadine is present in USP. The of nomenclature, structure, general physical form, manufacturers, ing process and controls, tests for analytical procedures and its and justification of specification, iner closure system and stability
	Stability studies		Stability study conditions: Real time: 30°C ± 2°C / 65° Accelerated: 40°C ± 2°C Batches: (DH-1501, DH-1501)	$/75\% \pm 5\%$ RH for 6 months
	Pharmaceutical equivalence and comparative dissolution profile		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.	
			brand leader that is Clarin Plough Corporation (Ba quality tests (Identification	the have been established against the nex 5mg tablet by M/s Scheringatch No CL9562) by performing the performing the performing that the performing the performing that the performing that the performing that the performing that the performing that the performance of the performa
			Clarinex 5mg tablet by N in Acid media (pH 1.0-	d against the same brand that is M/s Schering-Plough Corporation 1.2), Acetate buffer (pH-4.5) & The values for f1 and f2 are in the
	Analytical method v	alidation/verification of	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.	
		STABILI	TY STUDY DATA	
Manu	facturer of API	M/s Smaart Pharmace Maharashtra (India) -		MIDC, Ajanta Road, Jalgaon
API L	ot No.	SMAART/DSL/2021/00	03	
	iption of Pack ainer closure system)	Alu-Alu blister packed	in unit carton (2×10's)	
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		
Frequ	ency	Accelerated: 0, 3, 6 (Mor Real Time: 0, 3, 6 (Mor		
Batch	Batch No. DS-01		DS-02	DS-03
Batch Size 2,000 tab			2,000 tab	2,000 tab

Manufacturing Date 05-2022		05-2022	05-2022	
Date of Initiation 10-05-2022		10-05-2022	10-05-2022	
No. of Batches		03		
		Admini	istrative Portion	
13.	Reference of previous with stability study dat	approval of applications a of the firm (if any)	Not applicable	
14.	14. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Not provided	
15.	Documents for the pr approval from DRAP (for import of 5Kg SMAART/DSL/2021/003)	of Desloratadine (Batch No wherein name of M/s Panacea Pakistan was mentioned, attested abad dated 08-03-2021.
16.	6. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			
17.	. Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Not Provided	
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Submitted	
Rema	arks of Assessor (DD P	EC ^{XX)} :		
3.2.S.	regulatory authority of 4 Acceptance criteria/sp in CoA from Drug Su	country of origin pecifications for impuritient bstance re different from	of API manufacturer issued es (both single and total imputhose mentioned in USP. Juerformed under product Analysis)	urities) as mentioned stify it
	verification study 2 Results of specificity	parameter along with HP	PLC chromatograms (sample er product Analytical method	, standard,
3.2.P.	2.1.1 Compatibility of t		th excipient (Magnesium ste	earate) is not
Provided since said ingredient is not found i 3.2.P.8 Documents for import of API was submitted w pharmaceuticals Islamabad, Pakistan was ment dated 22-02-2021. Clarify it. 3.2.P.8 Compliance Record of HPLC software 21CFR			wherein the name of M/s Pan cioned, attested by AD (I&E)) DRAP Islamabad
	be provided.			
Decis	ion: Registration Boar	d deferred the case for	submission of reply to the	above cited shortcomings.
6.	Name, address of Appl Authorization Holder	licant / Marketing	M/s Pine Pharmaceuticals I Industrial estate. Rawat.	Plot No. 40. Street No. S-4,,RCCI,
	Name, address of Man	ufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI Industrial estate. Rawat.	
	Status of the applicant		⊠Manufacturer ☐ Importer	

 $\hfill\Box$ 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. 4616 dated 17/02/2023
Details of fee submitted	PKR 30,000/- dated 06/02/2023
The proposed proprietary name / brand name	Diflupine 150mg capsule
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: - Fluconazole150mg
Pharmaceutical form of applied drug	Tablet
Pharmacotherapeutic Group of (API)	Antimycotics for systemic use, triazole derivatives.
Reference to Finished product specifications	BP
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)	Diflucan 150mg Capsule By Pfizer Pakistan.
GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285 th mee of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
Name and address of API (pellets) manufacturer.	M/s Raj Pioneer Lab India, Pvt Ltd. 94-A,95-B & 96-A, Industrial area No. 01, A.B. Road Dewas, Madhya Prades 455001,India.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD temp Summarized information related to nomenclature, structure general properties, Solubility, physical form, manufacture description of manufacturing process and controls, impurispecifications, analytical procedures and its verification, be analysis and justification of specification, reference stand container closure system and stability studies of drug substant drug product is submitted.
Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure general properties, solubility, physical form, manufacture description of manufacturing process and control specifications, analytical procedures and its verification, by analysis and justification of specification, reference stand container closure system and stability studies of drug substitutions.
Stability studies	Stability study conditions: 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 Batches: RD/FCZ/001, RD/FCZ/002, RD/FCZ/003
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description manufacturing process and controls, specifications, analy procedure and its verification studies, batch analysis justification of specification, reference standard, contactors closure system and stability studies of drug product.

	dissolution profile		Pharmaceutical Equivalence have been established against the reference product that is Diflucan capsule 150mg (Batch No 1890017) by M/s Pfizer Pakistan by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation and DT) against Test Product Diflupine capsule (Batch No F001).	
			CDP has been performed against the same brand that Diflucan capsule 150mg (Batch No 1890017) in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.	
	Analytical method va product	alidation/verification of	Method verification stud accuracy, precision, specific	dies have submitted including city and system suitability.
		STABILIT	ΓΥ STUDY DATA	
Manu (pelle		M/s Raj Pioneer Lab Inc Road Dewas, Madhya P		5-A, Industrial area No. 01, A.B.
API L	Lot No.	FLC/FD/19/11/20-21		
	ription of Pack rainer closure system)	Alu-Alu blister		
Stabil	ity Storage Condition	Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		
Time	Period	Real time: 6 months Accelerated: 6 months		
Frequ	ency	Accelerated: 0, 3,6 (Mor Real Time: 0, 3,6 (Mon	The state of the s	
Batch	No.	F001	F002	F003
Batch	Size	1500 tablet	1500 tablet	1500 tablet
Manu	facturing Date	05-2022	05-2022	05-2022
Date	of Initiation	05-06-2022	05-10-2022	05-11-2022
No. o	f Batches		03	
		Admini	strative Portion	
1.	with stability study dat	•		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Not pro	ovided
3. I	3. I Documents for the procurement of API with approval from DRAP (in case of import).		Fluconazole (Batch No FLC M/s Panacea pharmaceu	uments for import of 25Kg of C/FD/19/11/20-21) wherein name of ticals Islamabad, Pakistan was (I&E) DRAP Islamabad dated 22-
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Provided	d
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		No	t Provided

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

- **1.6.5** Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- **3.2.S.4** Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
- **3.2.P.2** Parameters like Linearity and Range are not performed under product Analytical method verification study
- **3.2.P.2** Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study
- **3.2.P.8** Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 22-02-2021. Clarify it.
- **3.2.P.8** Analysis date mentioned for batches F002 and F003 at 0 month as 05/10/2022 (F002) and 05/11/2022 (F003) while date mentioned at 3^{rd} month and 6^{th} month as 08/08/2022 and 11/08/2022 respectively. Clarify it
- **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided.

sion: Registration Board deferred the case for	submission of reply to the above cited shortcomings.	
Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.	
Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot#40, Street#S-6,National Industrial Zone, Rawat, 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	
Dy. No. and date of submission	Dy. No. 4614 dated 17/02/2023	
Details of fee submitted	PKR 30,000/- dated 06/02/2023	
The proposed proprietary name / brand name	Moxopine 400mg tablets	
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Moxifloxacin as HCl400mg	
Pharmaceutical form of applied drug	Light yellow color, oblong, biconvex film coated tablets.	
Pharmacotherapeutic Group of (API)	Fluoroquinolone 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	Avelox 400mg tablets by M/s Bayer Corporation, Approved in USFDA	
For generic drugs (me-too status)	Moxiget 400mg tablets by M/s Getz Pharma Pakistan, Reg. No. 047117	

GMP status of the Finimanufacturer	shed product	New DML granted on 29.04.2022, approved in 285 th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
Module-II (Quality Overall Summary) For some series of the	M/s Rini Life Sciences Pvt. Limited. RR Industrial Estate, Khasra No 115/2/3, Bhawrasla, Sanwer road, 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, 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 Subs	stance)	Official monograph of Moxifloxacin HCl is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, 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 Module-III (Drug Product):		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: (MOX2000, MOX2001, MOX2002)
		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 equiva dissolution profile	alence and comparative	Pharmaceutical Equivalence have been established against the brand leader that is Avelox 400mg tablets (Batch No AT9562) by M/s Bayer Corporation by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). against Test product i.e Moxopine tablet 400mg (Batch No MP-01)
		CDP has been performed against the same brand that is Avelox 400mg tablets (Batch No AT9562) by M/s Bayer Corporation in Acid media (pH 1.0-1.2), Acetate buffer (pH-4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
Analytical method va	alidation/verification of	Method verification studies have submitted including, accuracy, precision, specificity and system suitability.
	STABILIT	TY STUDY DATA
anufacturer of API	M/s Rini Life Sciences l RR Industrial Estate, Kh	Pvt. Limited. nasra No 115/2/3, Bhawrasla, Sanwer road, India.
PI Lot No.	MH/002/09/2021	
escription of Pack	Alu-Alu blister packed i	n unit carton

(Con	tainer closure 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		
Frequ	uency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batcl	n No.	MP-01	MP-02	MP-03
Batcl	n Size	2000 tablets	2000 tablets	2000 tablets
Man	ufacturing Date	05-2022	05-2022	05-2022
Date	of Initiation	13-05-2022	13-05-2022	13-05-2022
No. o	of Batches		03	3
		Admin	istrative Portion	
1.	Reference of previous with stability study da	approval of applications ta of the firm (if any)		Nil
2. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.			Not provided	
3.	3. Documents for the procurement of API with approval from DRAP (in case of import).		Moxifloxacin HCl GESAC2/3 dated 0	ed documents for import of 50Kg of (Batch No MH/002/09/2021) invoice no 04.04.2022 wherein name of M/s Panacea amabad, Pakistan 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		1	Not provided	
6.		a logger for temperature ing of stability chambers ated)		

- **1.6.5** Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
- **3.2.S.4** Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
- **3.2.P.2** Parameters like Linearity and Range are not performed under product Analytical method verification study
- **3.2.P.2** Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study.
- **3.2.P.2** Quantity of Lactose monohydrate used in innovator product as 68mg while firm used 87.8mg Lactose monohydrate in instant formulation. Justify it.
- **3.2.P.8** Documents for import of API (invoice no. GESAC2/3 dated 04.04.2022) was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, Clarify it. Moreover, approval from DRAP has not been provided.
- **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided.

Agenda of Evaluator PEC-XXI

Agenda Item No. 01: Priority Applications of Human Drugs Locally Manufactured (New DML) applied on Form - 5F.

Case 01: M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura was granted License on 28-04-2022 with following sections: -

- i. Tablet (General)
- ii. Oral Dry Powder Suspension (General)
- iii. Capsule (General)
- iv. Sachet (General)

59.	Name, address of Applicant / Marketing Authorization Holder	M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura.		
	Name, address of Manufacturing site.	M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura.		
	Status of the applicant	 ☑ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver) ☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP) ☑ Domestic sale ☐ Export sale ☐ Domestic and Export sales 		
	Status of application			
	Intended use of pharmaceutical product			
	Dy. No. and date of submission	Dy. No. 5683 dated 28-02-2023		
	Details of fee submitted	Slip No. 50746387584 PKR 30,000/- dated 02-02-2023		
	The proposed proprietary name / brand name	D-Dex 30mg Capsule Each Capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5% w/w Eq. to Dexlansoprazole30mg		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit			
		(Innovator's Specification)		
	Pharmaceutical form of applied drug	White to greyish white colored dual delayed releast pellets filled in hard gelatin capsule shell no.3 havin light green color body and cap packed in Alu-Al blister		
	Pharmacotherapeutic Group of (API)	A02BC06, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.		
	Reference to Finished product specifications	Innovator's Specification		
	Proposed Pack size	1x10's, 2x7's, 3x10's, 10x10's		
	Proposed unit price	As per SRO		

The status in reference regulatory authorities	Dexilant 30 mg Capsules of M/s TAKEDA PHARMS USA (USFDA Approved).
For generic drugs (me-too status)	Razodex 30mg Capsule (Reg. No. 086976) of M/s Getz Pharma.
GMP status of the Finished product manufacturer	New DML granted dated 28-04-2022.
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. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)	Official monograph of Dexlansoprazole is present Inhouse. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies	Stability study conditions: Real time: $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$ RH for 36 months Accelerated: $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%$ RH for 06 months Batches: DLP125T, DLP124T, DLP123T,
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Razodex 30mg Capsule by Getz Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).
	CDP has been performed against the same brand that is Razodex 30mg Capsule by Getz Pharma in Acid media (pH 1.2) Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
Analytical method validation / verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity and System Suitability.

STABIL	ITY STUDY DATA			
Manufacturer of API		M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad		
API Lot	No.	DLP881		
_	on of Pack er closure system)	Alu-Alu blister packed in unit carton (3×10'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 Per	iod	Real Time: 06 months Accelerated: 06 month	s	
Frequenc	у	Accelerated: 0, 3, 6 (Macelerated: 0, 3, 6 (The state of the s	
Batch No).	CT007	CT008	CT009
Batch Siz	ze e	1200 Capsules	1200 Capsules	1200 Capsules
Manufact	turing Date	15-07-2022	15-07-2022	15-07-2022
Date of I	nitiation	22-07-2022	22-07-2022	22-07-2022
No. of Ba	atches	03		
Adminis	trative Portion			
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.		A •	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Copy of Invoice No. 803107 Dated 29-06-2022 from M/s Vision Pharmaceuticals (local source) is submitted.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Audit trail reports on prod	uct testing is submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Sub	mitted

Remarks of Evaluator:

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

- i. The name of Firm as mentioned on enclosed DML is "M/s ICU Pharmaceuticals" whereas the Firm have mentioned the name as "M/s ICU Pharmaceuticals (SMC) (Pvt.) Ltd." throughout their application.
- ii. 2.3.P.5.6 In Justification of Specifications, it has been mentioned that D-Dex 30mg Capsules are as per USP Specifications whereas in the rest of the application it has been mentioned as per In-house / Innovator's Specifications.
- iii. 2.3 P.8.2 (a) In Stability Protocol for Commitment Batches, Testing Frequency has been mentioned as 0,3,6 Months only, the same shall be as per claimed Shelf Life of the Product.

- iv. 3.2.P.2.2.1 In Tables given for Comparative Dissolution Profile Results, Buffer Stage pH 5.5 and pH 4.5 have been mentioned for same results in a table. Also Buffer Stage pH 7.0 and pH 6.8 have been mentioned for same results in a table.
- v. 2.3.1 CTD Introduction has been mentioned of Moringa Pharma. Clarification is sought.

Registration Board deferred the case for submission of reply to the above cited shortcomings.		
Name, address of Applicant / Marketing Authorization Holder	M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura.	
Name, address of Manufacturing site.	M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura.	
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. 5682 dated 28-02-2023	
Details of fee submitted	Slip No. 480770249565 PKR 30,000/- dated 02-02-2023	
The proposed proprietary name / brand name	D-Dex 60mg Capsule	
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5% w/w Eq. to Dexlansoprazole60mg (Innovator's Specification)	
Pharmaceutical form of applied drug	White to greyish white colored dual delayed release pellets filled in hard gelatin capsule shell no.3 having light green color body and cap packed in Alu-Alu blister	
Pharmacotherapeutic Group of (API)	A02BC06, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.	
Reference to Finished product specifications	Innovator's Specification	
Proposed Pack size	1x10's, 2x7's, 3x10's, 10x10's	
Proposed unit price	As per SRO	
The status in reference regulatory authorities	Dexilant 60mg Capsules of M/s TAKEDA PHARMS USA (USFDA Approved).	
For generic drugs (me-too status)	Razodex 60mg Capsule (Reg. No. 086977) of M/s Getz Pharma.	
GMP status of the Finished product manufacturer	New DML granted dated 28-04-2022.	

Name and addres	s of API manufacturer.	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
Module-II (Quali	ty Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
Module III (Drug	Substance)	Official monograph of Dexlansoprazole is present Inhouse. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies		Stability study conditions: Real time: $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$ RH for 36 months Accelerated: $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%$ RH for 06 months Batches: DLP125T, DLP124T, DLP123T,
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 comparative disso	equivalence and olution profile	Pharmaceutical Equivalence have been established against the brand leader that is Razodex 60mg Capsule by Getz Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).
		CDP has been performed against the same brand that is Razodex 60mg Capsule by Getz Pharma in Acid media (pH 1.2) Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
Analytical method validation / verification of product		Method validation studies have been submitted including linearity, range, accuracy, precision, specificity and System Suitability.
STABILITY STUDY DAT	Γ A	
Manufacturer of API	M/s Vision Pharmaceu	ticals rial Triangle, Kahuta Road, Islamabad
API Lot No.	DLP881	
Description of Pack (Container closure system)	Alu-Alu blister packed	in unit carton (3×10's)

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 Per	Time Period Real Time: 06 months Accelerated: 06 months		s	
Frequenc	у	Accelerated: 0, 3, 6 (Mo	· · · · · · · · · · · · · · · · · · ·	
Batch No).	CT010	CT011	CT012
Batch Siz	ze	1200 Capsules	1200 Capsules	1200 Capsules
Manufact	turing Date	07-2022	07-2022	07-2022
Date of I	nitiation	26-07-2022	26-07-2022	26-07-2022
No. of Ba	atches	03		
Adminis	trative Portion			
1.		evious approval of bility study data of the		Nil
2.	_	ML/GMP certificate of issued by concerned of country of origin.	1 0	e No. F.3-26/2019-Addl.Dir. 08-2022 is submitted.
3.	Documents for the pr approval from DRAP	ocurement of API with (in case of import).		107 Dated 29-06-2022 from ls (local source) is submitted.
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			Sub	mitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Audit trail reports on prod	duct testing is submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Sub	omitted

Remarks of Evaluator:

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

- vi. The name of Firm as mentioned on enclosed DML is "M/s ICU Pharmaceuticals" whereas the Firm have mentioned the name as "M/s ICU Pharmaceuticals (SMC) (Pvt.) Ltd." throughout their application.
- vii. 2.3.P.5.6 In Justification of Specifications, it has been mentioned that D-Dex 60mg Capsules are as per USP Specifications whereas in the rest of the application it has been mentioned as per In-house / Innovator's Specifications.
- viii. 2.3 P.8.2 (a) In Stability Protocol for Commitment Batches, Testing Frequency has been mentioned as 0,3,6 Months only, the same shall be as per claimed Shelf Life of the Product.
- ix. 3.2.P.2.2.1 In Tables given for Comparative Dissolution Profile Results, Buffer Stage pH 5.5 and pH 4.5 have been mentioned for same results in a table. Also Buffer Stage pH 7.0 and pH 6.8 have been mentioned for same results in a table.
- x. 2.3.1 CTD Introduction has been mentioned of Moringa Pharma. Clarification is sought.

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

Case 02: M/s Himark Laboratories Private Limited Plot 37-A, Sundar Industrial Estate Lahore was granted New DML on 26-09-2019 with following sections: -

- i. Tablet (General & General Antibiotics) Section.
- ii. Capsule (General & General Antibiotics) Section.
- iii. Dry Powder Suspension (General & General Antibiotics) Section.
- iv. Sachet (General) Section.
- v. Oral Liquid Syrup Section.
- vi. Cream /Ointment (General) Section.

561.	Name, address of Applicant / Marketing	M/s Himark Laboratories Private Limited Lahore	
	Authorization Holder		
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited Plot 37-A, Sundar Industrial Estate Lahore	
	Status of the applicant		
		☐ 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. 4930 dated 21-02-2023	
	Details of fee submitted	Slip No. 890870611016 PKR 20,000/- dated 31-01-2023	
		Slip No. 02554272360 PKR 10,000/- dated 04-11-2021	
	The proposed proprietary name / brand name	Levomark 250 mg film coated tablet	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet contains: Levofloxacin hemihydrate equivalent to Levofloxacin USP 250mg	
		(USP Specifications)	
	Pharmaceutical form of applied drug	Light yellow oblong film coated tablet	
	Pharmacotherapeutic Group of (API)	J01MA12 Anti-infective for Systemic Use, Fluoroquinolones	
	Reference to Finished product specifications	USP Specifications	
	Proposed Pack size	1 ×10's	
	Proposed unit price	As per SRO	
	The status in reference regulatory authorities	Levofloxacin 250 mg Film-coated Tablets by Accord Healthcare Limited UK (MHRA Approved).	
	For generic drugs (me-too status)	Leflox 250mg Tablet (Reg. No. 026164) by Getz Pharma.	
	GMP status of the Finished product manufacturer	New license granted on 26 – 09 – 2019.	

			Zhejiang Apeloa Kangyu Pharmaceutical Co. Ltd. 333 Jiangnan Road, hengdian, Dongyang, Zhejiang Province, 322118 PR China
			Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)		Official monograph of Levofloxacin hemihydrate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and impurities and water content have been performed, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies Module-III (Drug Product):		Stability study conditions: Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\%\text{RH}$ for 36 months Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\%$ RH for 6 months Batches:(LFA-V-20120801ES, LFA-V-20120802ES, LFA-V-20120803ES).
			The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure including dissolution testing and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical comparative dissoluti	equivalence and on profile	Pharmaceutical Equivalence have been established against the brand Leflox 250mg Tablet by Getz Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).
			CDP has been performed against the same brand that is Leflox 250mg Tablet by Getz Pharma in Acid media (pH 1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation / verification of product		Method verification studies have submitted including precision, accuracy and specificity.
STABIL	ITY STUDY DATA		
Manufact			yu Pharmaceutical Co. Ltd. nengdian, Dongyang, Zhejiang Province, 322118 PR
API Lot I	API Lot No. KY-LFA-M20190968B		E
	on of Pack er closure system)	Alu-Alu blister packed	in unit carton (1×10's)

Stability	Stability Storage Condition Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 4$ Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 4$			
Time Period Real Time: 06 Months Accelerated: 06 Months		s		
Frequenc	у	Accelerated: 0,3,6 (Mo Real Time: 0,3,6 (Mon		
Batch No).	T-61	T-62	T-63
Batch Siz	ze	1500 tab	1500 tab	1500 tab
Manufact	turing Date	04-2020	04-2020	04-2020
Date of I	nitiation	24-04-2020	24-04-2020	24-04-2020
No. of Ba	atches	03		
Adminis	trative Portion			
1.		evious approval of bility study data of the]	Nil
2.		issued by concerned		No. ZJ20190145 issued by ninistration is submitted.
3.	Documents for the pr approval from DRAP	ocurement of API with (in case of import).		ice No. 2020APE4256 dated ed. However approval from
4. Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.			Sub	mitted
5.		of HPLC software il reports on product	Not St	ubmitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Sub	mitted

Remarks of Evaluator:

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

- i. Latest GMP Inspection Report (not older than 03 years) is required.
- ii. In Analytical Procedure for Levomark 250mg Film Coated Tablet (Document # SAP-106), under test for Dissolution, Medium has been mentioned as 0.1N HCl as well as 0.01N HCl. Clarification is required.
- iii. In Stability Study Protocol for Levomark 250mg Film Coated Tablet (Document # SSP-024), the Objective has been stated as "to carry out stability of Levomark 250mg film coated Tablet (Loratadine)". Clarification is required.
- iv. Evidence of approval from DRAP (concerned Assistant Director I&E) for procurement of Levofloxacin hemihydrate, API Lot No. KY-LFA-M20190968E is required.
- **v.** Trial Batches were manufactured and placed on Stability in April 2020, however the application for Registration has been filed in February 2023 (with 06 Months Stability Data). Reason for delayed submission is sought.

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

Agenda of Evaluator PEC-XXII

Case no. 01: Registration applications of New DML (Veterinary)

New DML

- M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala. I. CLB in its 289th meeting held on 23-01-2023 has considered and approved the grant of DML by way of formulation with following sections.
 - 1. Oral Liquid (General) Veterinary
 - 2. Oral Liquid (General Antibiotic) Veterinary
 - 3. Oral Powder (General) Veterinary
 - 4. Oral Powder (General Antibiotic) Veterinary

	Accordingly, firm has app	lied f	or following products for co	onsideration by the Registration Board:
	Section		No. of Products applied	No. of Molecules applied
	Oral Liquid (General Antibiotic)		23	10
			Oral Liquid (General Anti	
562	Name and address of			lot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant		Kamonke, Gujranwala.	
	Brand Name +Dosage Form	1 +	Feniczone-11 Oral Liquid	
	Strength			
	Composition		Each 100ml contains:	
			Florfenicol11g	0.2411
			Colistin Sulphate (BP)5	
	Diary No. Date of R& I & f	ee		-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group		Antibiotic	
	Type of Form		Form 5	
	Finished product		Innovator Specifications	
	Specification			
	Pack size & Demanded P	rice	50ml, 100ml, 250ml, 500m	nl, 1000ml, 5000ml: Decontrolled
	Me-too status		Flo Raft Oral Liquid of M	/s Nawal Pharmaceuticals,
	Me-too status		Rawalpindi. (Reg. No. 078	
	GMP status			23, Last inspection: 22-12-2022
	Remarks of the Evaluator			
	Decision: Approved with p	pack		
563			_	lot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant		Kamonke, Gujranwala.	
	Brand Name +Dosage Form	1 +	Feniczone-12 Oral Liquid	
	Strength			
	Composition		Each 100ml contains:	
			Florfenicol10g	. ~
	D: N D (CD 0 1 0 0	•	Colistin Sulphate (BP)2	
	Diary No. Date of R& I & f	ee		-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group		Antibiotic	
	Type of Form		Form 5	
	Finished product		Innovator Specifications	
	Specification			
	Pack size & Demanded P	rice		nl, 1000ml, 5000ml: Decontrolled
	Me-too status		Co-Flor Liquid Mfg. by M (Reg. No. 078326)	I/s Wimits Pharmaceuticals, Lahore.
	GMP status			23, Last inspection: 22-12-2022
	Remarks of the Evaluator			-
	Decision: Approved with	pack	size of upto 1Ltr.	

564.	Name and address of	M/a OAC International Diet No. 152/155 Myatefacked Takeil
504.	manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Feniczone-23 Oral Liquid
	Strength	Temezone-25 Orai Elquid
	Composition	Each 1000ml contains:
	Composition	Florfenicol230g
		Colistin Sulphate (BP)500 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8103 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml : Decontrolled
	1 dek size & Bellianded i fice	SAFLOR-PLUS ORAL LIQUID Mfg. by M/s Sanna
	Me-too status	Laboratories, Faisalabad. (Reg. No. 088109)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	2112 155600 511 10 02 2025, 2850 115500001 22 12 2022
	Decision: Approved with pack	size of upto 1Ltr.
565.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Feniczone-25 Oral Liquid
	Strength	-
	Composition	Each ml contains:
		Florfenicol250mg
		Colistin Sulphate (BP)0.5 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8104 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml : Decontrolled
	Me-too status	Poliflor Oral Liquid Mfg. by M/s Hawk Bio Pharma, Rawalpindi.
		(Reg. No. 078383)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	
566.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Feniczone-10 Oral Liquid
	Strength	Each 100 ml contains:
	Composition	Each 100 ml contains: Florfenicol10g
		Colistin Sulphate (BP)50 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8105 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	7 1	Innovator Specifications
	Finished product	Innovator specifications
	Specification Pack size & Demonded Brice	50ml 100ml 250ml 500ml 1000ml 5000ml December 11 1
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml: Decontrolled
	Me-too status	Florobex-C Oral Liquid Mfg. by M/s. Elegance Pharmaceuticals,
		Rawalpindi. (Reg. No. 078286)
	GMP status Remarks of the Evaluator	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Decision: Approved with pack s	size of unto 11 tr
	Decision. Approved with pack s	ուշ ու սիտ ար

567.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
2071	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Enc-Zone 10 Oral Liquid
	Strength	200 200 10 0100 21400
	Composition	Each 100 ml contains:
	T STATE OF THE STA	Enrofloxacin (BP Vet)10g
		Colistin Sulphate (BP)50 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8108 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	1 dek size & Demanded i nee	Coliflox Solution Mfg. by M/s. Selmore Pharmaceuticals,
	Me-too status	Lahore. (Reg. No. 071082)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	
568.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Enc-Zone 200 Oral Liquid
	Strength	
	Composition	Each 1000 ml contains:
		Enrofloxacin (BP Vet)200g
		Colistin Sulphate (BP)500 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8109 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
		Floxatin 70 Oral Liquid Mfg. by M/s. elegance Pharmaceuticals,
	Me-too status	Rawalpindi. (Reg. No. 078282)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	size of upto 1Ltr.
569.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Enc-Zone 48 Oral Liquid
	Strength	•
	Composition	Each ml contains:
		Enrofloxacin (BP Vet)100mg
		Colistin Sulphate (BP)48 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8110 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	1 ack Size & Demanded File	
	Me-too status	Enromax Liquid Mfg. by M/s. Biogen Pharmaceuticals, Rawat. (Reg. No. 075618)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	•
	Decision: Approved with pack	size of upto 1Ltr.
	**	

570.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
370.	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Enc-Zone 52 Oral Liquid
	Strength	1
	Composition	Each 100ml contains:
	_	Enrofloxacin (BP Vet)10g
		Colistin Sulphate (BP)52 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8111 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	Me-too status	Bioenrocolis Liquid Mfg. by M/s. Elegance Pharmaceuticals, Rawalpindi. (Reg. No. 073916)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	2112 100000 011 10 02 2020, 2000 1100000000 22 12 2022
	Decision: Approved with pack	size of upto 1Ltr.
571.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Cina-Zone 50 Oral Solution
	Strength	
	Composition	Each 1000ml contains:
		Enrofloxacin (BP Vet))75g
		Sulphamethoxypyradazine (BP Vet)50g
		Sulphamethazine (USP)50g
		Trimethoprim (BP)25g
	Diary No. Date of R& I & fee	Dy. No. 8113 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	Me-too status	Sulphacina Oral solution Mfg. by M/s. Bio-Oxime
	GMP status	Pharmaceuticals, Faisalabad. (Reg. No. 074786) DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	i. Firm has applied a similar formulation with only difference being the strength of Sulphamethoxypyradazine as 75mg/ml but the claimed
		dosage form is Oral Suspension. Clarification required in
		this regard.
572		f formulation by expert working group on veterinary drugs.
572.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Cina-Zone 75 Oral Suspension
	Strength	Cina Zono 13 Orai baspension
	Composition	Each ml contains:
	r	Enrofloxacin (BP Vet)75mg
		Sulphamethoxypyradazine (BP Vet)75mg
		Sulphamethazine (USP)50mg
		Trimethoprim (BP)25mg
	Diary No. Date of R& I & fee	Dy. No. 8112 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
·		

	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	Me-too status	Cina T.S Oral Suspension Mfg. by M/s. Vety-Care Pharmaceuticals, Islamabad. (Reg. No. 031456)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	i. Firm has already applied a similar formulation with only difference being the strength of Sulphamethoxypyradazine as 50mg/ml but the claimed dosage form is Oral Solution. Clarification required in
		this regard.
	Decision: Deferred for review o	f formulation by expert working group on veterinary drugs.
573.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	T.S Zone 48 Oral Solution
	Composition	Each 100ml contains: Trimethoprim (BP)8g Sulphadiazine (BP)40g
	Diary No. Date of R& I & fee	Dy. No. 8114 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	Me-too status	Fastrim-48 Liquid Mfg. by M/s. Mallard Pharmaceuticals,
		Multan. (Reg. No. 109803)
	GMP status Remarks of the Evaluator	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Decision: Approved with pack	size of unto 11 tr
574.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
374.	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Toltrazone-5 Oral Solution
	Strength	
	Composition	Each 100ml contains:
	•	Toltrazuril5g
	Diary No. Date of R& I & fee	Dy. No. 8115 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Coccidiostat/Antiprotozoal agent
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	Me-too status	Toltrasel Solution Mfg. by M/s. Selmore Pharmaceuticals,
	GMP status	Lahore. (Reg. No. 071081) DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	Divid Issued on 10-02-2023, Last hispection. 22-12-2022
	Decision: Approved with pack	size of unto 11 tr
575.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Toltrazone-3 Oral Solution
	Strength	
	Composition	Each 1000ml contains: Toltrazuril30g
	Diary No. Data of D % I % for	
	Diary No. Date of R& I & fee	Dy. No. 8116 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Coccidiostat/Antiprotozoal agent
	Pharmacological Group	Coccidiosiai/Antiprotozoai agent

	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	1
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	Me-too status	Toltrasol 3% Liquid Mfg. by M/s. Intervac Pharma, Sheikhupura. (Reg. No. 069661)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	2 *** 150000 01 10 02 2020, 2000 115p0001010 22 12 2022
	Decision: Approved with pack	size of upto 1Ltr.
576.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Toltrazone-2.5 Oral Solution
	Strength	
	Composition	Each 1000ml contains: Toltrazuril25g
	Diary No. Date of R& I & fee	Dy. No. 8117 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Coccidiostat/Antiprotozoal agent
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification Specification	anno (uto) specificanions
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Ultrazuriq Oral Solution Mfg. by M/s. Baariq Pharmaceuticals,
	Wic-too status	Lahore. (Reg. No. 071093)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	
577.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Colizone 48 Oral Solution
	Composition	Each 100ml contains: Colistin Sulphate (BP)48 M.I.U
	Diary No. Date of R& I & fee	Dy. No. 8118 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	Me-too status	Arkol Liquid Mfg. by M/s. Attabak Pharmaceuticals, Islamabad. (Reg. No. 028890)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	, , , , , , , , , , , , , , , , , , , ,
	Decision: Approved with pack	size of upto 1Ltr.
578.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Colizone 200 Oral Solution
	Strength	
	Composition	Each 1000ml contains: Colistin Sulphate (BP)2,000,000,000 I.U
	Diary No. Date of R& I & fee	Dy. No. 8119 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	*
L	Specification	

	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
		Colibar Oral Solution Mfg. by M/s. Baariq Pharmaceuticals,
	Me-too status	Lahore. (Reg. No. 075784)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	size of upto 1Ltr.
579.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Tilmizone-25 Oral Solution
	Strength	
	Composition	Each ml contains:
		Tilmicosin Phosphate (USP)250mg
	Diary No. Date of R& I & fee	Dy. No. 8120 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
		Tilcosin Oral Solution Mfg. by M/s. Selmore Pharmaceuticals,
	Me-too status	Lahore. (Reg. No. 035150)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	, <u> </u>
	Decision: Approved with pack	size of upto 1Ltr.
		000/- for correction in formulation, as per notification No.F.7-
	11/2012-B&A/DRAP dated 07-	05-2021, before issuance of registration letter.
580.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Enrozone-20 Oral Liquid
	Composition	Each ml contains:
	Composition	Enrofloxacin (BP Vet)200mg
	Diamy No. Data of D. Pr. I. Pr. foo	, ,
	Diary No. Date of R& I & fee	Dy. No. 8121 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Antibiotic
	Pharmacological Group	
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	Me-too status	Enroxsel 20 Oral Liquid Mfg. by M/s. Selmore Pharmaceuticals, Lahore. (Reg. No. 049364)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	, , , , , , , , , , , , , , , , , , ,
	Decision: Approved with pack	size of upto 1Ltr.
581.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Enrozone-10 Oral Liquid
	Strength	
	Composition	Each ml contains:
		Enrofloxacin (BP Vet)100mg
	Diary No. Date of R& I & fee	Dy. No. 8122 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	*
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
i .	1 acr bize & Demanded I file	

		Enrocin-10 20 Oral Solution Mfg. by M/s. Jfrin Pharmaceuticals,
	Me-too status	Karachi. (Reg. No. 043251)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	size of upto 1Ltr.
582.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Enrozone-25 Oral Liquid
	Composition	Each 100ml contains:
		Enrofloxacin (BP Vet)25g
	Diary No. Date of R& I & fee	Dy. No. 8123 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
		Flunix Liquid Mfg. by M/s. Leads Pharma, Islamabad. (Reg. No.
	Me-too status	043251)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	size of upto 1Ltr.
583.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Nora-Zone Oral Drench
	Strength	E 1 100 1
	Composition	Each 100ml contains:
		Norfloxacin (BP)20g Aminophylline (BP)8g
		Guaifenesin (USP)20g
	Diary No. Date of R& I & fee	Dy. No. 8124 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
		Nor Plus-20% Oral Liquid Mfg. by M/s. Bio Labs, Islamabad.
	Me-too status	(Reg. No. 033241)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review o	f formulation by expert working group on veterinary drugs.
584.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Eca-Zone Oral Solution
	Strength	E 1 1000 1 4 '
	Composition	Each 1000ml contains:
		Enrofloxacin (BP Vet)20g Colistin Sulphate (BP)35g
		Amantadine (BP)40g
	Diary No. Date of R& I & fee	Dy. No. 8125 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic Service 12-03-2023, Rs. 30,000/- Bated 13-03-2023
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	Innovator opecinications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	1 ack size & Demanded Price	John, 100mi, 230mi, Jouni, 1 L, 2.3 L, 3 L . Decomoned

	Me-too status	Amantaflox-C Mfg. by M/s. Baariq Pharma, Lahore. (Reg. No. 073946)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review	Designer Deferred for review of formulation by expert working group on veteringry drugs

Section	No. of Products applied	No. of Molecules applied
Oral Liquid (General)	10	10

10	10
Oral Liquid (General)	

585.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
363.	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Ati-Zone Oral Drench
	Strength	The Bond of the Bronon
	Composition	Each 100ml contains:
		Albendazole (BP)10g
		Tricalbendazole (BP)12g
		Ivermectin (USP)0.2g
	Diary No. Date of R& I & fee	Dy. No. 8126 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
		Thunder Drench Mfg. by M/s. Star Laboratories, Lahore. (Reg.
	Me-too status	No. 058941)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of testing facility for the applied formulation.	
586.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Ati-Zone Oral Drench
	Strength	
	Composition	Each ml contains:
		Oxyclozanide (BP Vet)62.5mg
		Oxyfendazole (BP Vet)22.65mg
		Cobalt Sulphate1.67mg
	Diamy No. Data of D.C. I. C. for	Sodium Selenite (BP)0.50mg
	Diary No. Date of R& I & fee	Dy. No. 8127 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic
	Pharmacological Group	
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Oxfendaox Plus Oral Drench Mfg. by M/s. Baariq
		Pharmaceuticals, Lahore. (Reg. No. 075786)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
505		ation of testing facility for the applied formulation.
587.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Oxazone Oral Drench
	Strength	Each ml contains:
	Composition	
		Oxyfendazole (BP Vet)22.65mg
	Diary No. Date of R& I & fee	Dy. No. 8128 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023

	Pharmacological Group	Anthelmintic
1	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	innovator specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Fack size & Demanded Fince	Oxasel Drench Mfg. by M/s. Selmore Pharmaceuticals, Lahore.
	Me-too status	(Reg. No. 071084)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	Divid issued on 10 02 2023, East inspection. 22 12 2022
	Decision: Approved with pack	size of upto 1Ltr.
588.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Levazone Oral Drench
	Strength	
	Composition	Each 100ml contains:
		Levamisole HCl (BP Vet)1.5g
		Oxyclozanide (BP Vet)3g
	Diary No. Date of R& I & fee	Dy. No. 8129 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	Me-too status	Clozasol Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore.
		(Reg. No. 078328)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
589.	Decision: Approved with pack Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
307.	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Levamizone Oral Drench
	Brand Name +Dosage Form + Strength	Levamizone Oral Drench
	Brand Name +Dosage Form + Strength Composition	Levamizone Oral Drench Each ml contains:
	Strength Composition	Each ml contains: Levamisole HCl (BP Vet)15mg
	Strength	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic
	Strength Composition Diary No. Date of R& I & fee	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic
	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications
	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore.
	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078333)
	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore.
	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078333) DML Issued on 16-02-2023, Last inspection: 22-12-2022
500	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078333) DML Issued on 16-02-2023, Last inspection: 22-12-2022
590.	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack Name and address of	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078333) DML Issued on 16-02-2023, Last inspection: 22-12-2022 size of upto 1Ltr. M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
590.	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack Name and address of manufacturer / Applicant	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078333) DML Issued on 16-02-2023, Last inspection: 22-12-2022 size of upto 1Ltr. M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
590.	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack Name and address of manufacturer / Applicant Brand Name +Dosage Form +	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078333) DML Issued on 16-02-2023, Last inspection: 22-12-2022 size of upto 1Ltr. M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
590.	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078333) DML Issued on 16-02-2023, Last inspection: 22-12-2022 size of upto 1Ltr. M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
590.	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack Name and address of manufacturer / Applicant Brand Name +Dosage Form +	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078333) DML Issued on 16-02-2023, Last inspection: 22-12-2022 size of upto 1Ltr. M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala. Scour-Zone Oral Solution
590.	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078333) DML Issued on 16-02-2023, Last inspection: 22-12-2022 size of upto 1Ltr. M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala. Scour-Zone Oral Solution Each ml contains:
590.	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078333) DML Issued on 16-02-2023, Last inspection: 22-12-2022 size of upto 1Ltr. M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala. Scour-Zone Oral Solution Each ml contains: Sulphadiazine (BP)33.500mg Neomycin Sulphate (BP)1.800mg Pectin (USP)7.100mg
590.	Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Each ml contains: Levamisole HCl (BP Vet)15mg Dy. No. 8130 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Anthelmintic Form 5 Innovator Specifications 50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled Levamit Drench Mfg. by M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078333) DML Issued on 16-02-2023, Last inspection: 22-12-2022 size of upto 1Ltr. M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala. Scour-Zone Oral Solution Each ml contains: Sulphadiazine (BP)33.500mg Neomycin Sulphate (BP)1.800mg

		II ' M (1 1D '1 (D1 E) 0.040
		Hyoscine Methyl Bromide (Ph. Eur)0.040mg
		Kaolin (BP)103.300mg
	D: N D (CD0 10 C	Vitamin B2 (BP)0.200mg
	Diary No. Date of R& I & fee	Dy. No. 8131 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antidiarrheal
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	Me-too status	Scour-X Mfg. by M/s. Selmore Pharmaceuticals, Lahore. (Reg. No. 029661)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	,
	Decision: Deferred for review o	f formulation by expert working group on veterinary drugs.
591.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Sulpha-Zone Oral Solution
	Strength	•
	Composition	Each 100ml contains:
	•	Sulphadimidine Sodium (BP)33.3mg
	Diary No. Date of R& I & fee	Dy. No. 8132 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
		Form 5
	Type of Form	
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Sulphamic 33.33% Oral Liquid Mfg. by M/s. Intervac (Pvt.) Ltd.,
		Sheikhupura. (Reg. No. 062197)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
502	Decision: Approved with pack	
592.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Albendazole Oral Suspension
	Strength	E 1 100 1 4 '
	Composition	Each 100ml contains:
		Albendazole (BP)2.5g Cobalt Chloride (BP)0.075g
		Sodium Selenite (BP)0.035g
	Diary No. Date of R& I & fee	Dy. No. 8133 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
		Form 5
	Type of Form	
	Finished product	Innovator Specifications
	Specification	50 1 100 1 250 1 500 1 1 2 2 5 7 5 7 5
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	Me-too status	Albenda Plus Suspension Mfg. by M/s. Farm Aid Group, Hattar. (Reg. No. 029670)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	*
		ation of testing facility for the applied formulation.
593.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Febendazone Oral Liquid
	Strength	1 "

	I a	T 1 100 1
	Composition	Each 100ml contains:
		Febendazole (USP)12.5g
		Cobalt Sulphate1.6g
		Zinc Carbonate0.6g
		Sodium Selenite (USP)3.0g
	Diary No. Date of R& I & fee	Dy. No. 8134 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	Me-too status	Fenfas Liquid Mfg. by M/s. Intervac (Pvt.) Ltd., Sheikhupura.
	Me-too status	(Reg. No. 058753)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for confirm	ation of testing facility for the applied formulation
594.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Darvin Oral Solution
	Strength	
	Composition	Each 100ml contains:
		Sulphaquinoxaline (USP)7.68g
		Diaverdine1.92g
	Diary No. Date of R& I & fee	Dy. No. 8135 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L: Decontrolled
	3.6	Darvifas Oral Solution Mfg. by M/s. Intervac (Pvt.) Ltd.,
	Me-too status	Sheikhupura. (Reg. No. 046610)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	•
	Decision: Approved with pack	size of upto 1Ltr.
	****	-

Section	No. of Products applied	No. of Molecules applied
Oral Powder (General)	12	09

Oral Powder (General)

595.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Ectozone-96 Powder
	Composition	Each gram contains: Trichlorfon (USP)960mg
	Diary No. Date of R& I & fee	Dy. No. 8091 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Ectofon Water Soluble Powder Mfg. by M/s. Prix Pharmaceuticals, Lahore. (Reg. No. 041295)

	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	size of upto 1Kg.
596.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Ectozone-98 Powder
	Strength	
	Composition	Each gram contains:
		Trichlorfon (USP)980mg
	Diary No. Date of R& I & fee	Dy. No. 8092 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Trifon Powder Mfg. by M/s. Selmore Pharmaceuticals, Lahore. (Reg. No. 071071)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	
597.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Ectozone-100 Powder
	Composition	Each gram contains: Trichlorfon (USP)1000mg
	Diary No. Date of R& I & fee	Dy. No. 8093 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	I-Trichlorophone Powder Mfg. by M/s. International Pharma Labs, Lahore. (Reg. No. 063617)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	
598.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	ES-Zone 300 Oral Powder
	Strength Composition	Each 100g contains:
		Sulphachloropyrazine Sodium as Sulphaclozine Sodium
		Monohydrate (USP)30g
	Diary No. Date of R& I & fee	Dy. No. 8094 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	•
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled
	Me-too status	Salcozine ST-30 Oral Powder Mfg. by M/s. Vetec Laboratories, Rawalpindi. (Reg. No. 097974)

	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	size of upto 1Kg.
599.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Frusazone-4 Powder
	Strength	7 1 1000
	Composition	Each 1000g contains:
		Sodium Chloride (BP)35g Magnesium Sulphate (BP)35g
		Manganese Sulphate1g
		Potassium Chloride4g
		Furosemide (BP)20g
		Calcium Carbonate (BP)45g
	Diary No. Date of R& I & fee	Dy. No. 8095 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
		10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg:
	Pack size & Demanded Price	Decontrolled
	Me-too status	F-Maars Powder Mfg. by M/s. D-Maarson Pharmaceuticals,
		Islamabad. (Reg. No. 078265)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
(00		ation of testing facility for the applied formulation.
600.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant Brand Name +Dosage Form +	Kamonke, Gujranwala. PCB-20 Oral Powder
	Strength	PCB-20 Ofai Fowder
	Composition	Each 100g contains:
	Composition	Paracetamol (BP)20g
		Vitamin E (USP)12.5g
		Vitamin C (BP)5g
		Sodium Bicarbonate (BP)12.5g
		Potassium Carbonate (BP)12.5g
	Diary No. Date of R& I & fee	Dy. No. 8096 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anti-inflammatory, Antipyretic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled
		Cemol Oral Powder Mfg. by M/s. Selmore Pharmaceuticals,
	Me-too status	Lahore. (Reg. No. 103909)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
		of formulation by expert working group on veterinary drugs.
601.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Parazone 6.7 Oral Powder
		Fact 1000s southing
	Composition	Each 1000g contains:
	Composition	Each 1000g contains: Acetylsalicylic Acid (BP)67g
	Composition	Acetylsalicylic Acid (BP)67g Vitamin C (BP)200g

		Potassium Chloride (BP)3g
	Diary No. Date of R& I & fee	Dy. No. 8097 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Analgesic/Vitamins
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Asperlyte-C Powder Mfg. by M/s. Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 074789)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	i	f formulation by expert working group on veterinary drugs.
602.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Amprozone-90 Water Soluble Powder
	Strength	Fool 1000 contains
	Composition	Each 1000g contains: Amprolium HCl (USP)900g
		· / -
	Diary No. Date of R& I & fee	Dy. No. 8098 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Coccidiostat
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Amprobar Water Soluble Powder Mfg. by M/s. Baariq Pharmaceuticals, Lahore. (Reg. No. 073955)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
60.0	Decision: Approved with pack	
603.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Amprozone-50 Water Soluble Powder
	Composition	Each 100g contains:
	Composition	Amprolium HCl (USP)50g
	Diary No. Date of R& I & fee	Dy. No. 8099 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Coccidiostat
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg:
		Decontrolled
	Me-too status	Amprocox-50 Water Soluble Powder Mfg. by M/s. Intervac (Pvt.) Ltd., Lahore. (Reg. No. 046601)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	
604.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Cocozone Oral Powder
	Strength	

	T	
	Composition	Each 100g contains:
		Sulphaquinoxaline (USP)16g
		Diaveridine4g
		Vitamin A (BP)0.40 MIU
		Vitamin K3 (USP)1g
	Diary No. Date of R& I & fee	Dy. No. 8100 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	•
		10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg:
	Pack size & Demanded Price	Decontrolled
		Cocoplus Oral Powder Mfg. by M/s. Intervac Pharmaceuticals,
	Me-too status	Lahore. (Reg. No. 046604)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
		of formulation by expert working group on veterinary drugs.
605.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Saans Oral Powder
	Strength	
	Composition	Each 1000g contains:
	1	Bromhexine HCl (BP)5000mg
		Prednisolone (BP)200mg
		Guaifenesin (USP)2600mg
	Diary No. Date of R& I & fee	Dy. No. 8101 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Mucolytic/corticosteroid/Expectorant
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	anno (uto) specificanions
	•	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg:
	Pack size & Demanded Price	Decontrolled
	Me-too status	Could not be confirmed in the applied combination.
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	i. Evidence of applied formulation/drug already approved
	Remarks of the Evaluator	by DRAP (generic / me-too status) alongwith registration
		number, brand name and name of firm could not be
		confirmed.
	Decision: Deferred for confirm	
606.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Bromozone Water Soluble Powder
	Strength	
	Composition	Each 100g contains:
	•	Bromhexine HCl (BP)5g
	Diary No. Date of R& I & fee	Dy. No. 8102 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Mucolytic Succession Success
	Type of Form	Form 5
	* *	
	Finished product	Innovator Specifications
	Specification	10 00 50 100 050 500 11 101 105
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg:
		Decontrolled No. 1
	Me-too status	Bromex Water Soluble Powder Mfg. by M/s. Attabak
		Pharmaceuticals, Islamabad (Reg. No. 058891)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022

Remarks of the Evaluator

Decision: Approved with pack size of upto 1Kg.

Section	No. of Products applied	No. of Molecules applied
Oral Powder (Antibiotic)	18	10

Oral Powder (Antibiotic)

607.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	CNC-Zone Oral Powder
	Strength	Each 100g contains:
	Composition	Each 100g contains: Neomycin as Sulphate (BP)7g
		Chlortetracyclin HCl (USP)8g
		Colistin Sulphate (BP)0.4g
	Diary No. Date of R& I & fee	Dy. No. 8073 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	The state of the s
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg : Decontrolled
		NCC Mix Mfg. by M/s. Prix Pharmaceuticals, Lahore (Reg. No.
	Me-too status	069678
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	
608.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Diarrozone Powder
	Composition	Each 12g contains:
		Neomycin sulphate (BP)400mg
		Streptomycin sulphate (BP)400mg
		Sulphaguanidine (BP)4g
		Kaolin (BP)4g
		Pectin (USP)400mg
		Bismuth Subnitrate (USP)2g
	Diamy No. Data of D % I % for	Vitamin A Acetate (BP)80000 IU
	Diary No. Date of R& I & fee	Dy. No. 8074 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic
	Pharmacological Group	Form 5
	Type of Form	
	Finished product	Innovator Specifications
	Specification	10 20 50 100 250 500 11 101 1251 251
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled
	Ma taa atatus	Diarroban Oral Powder Mfg. by M/s. Star Labs, Lahore (Reg. No.
	Me-too status	026438)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	•
609.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	LC-Zone Oral Powder
	Strength	

	Composition	Each gram contains:
	Composition	Lincomycin HCl (USP)100mg
		Colistin sulphate (BP)800000 IU
	Diary No. Date of R& I & fee	Dy. No. 8075 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	innovator opermeations
	Specification	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg:
	Pack size & Demanded Price	Decontrolled
	Me-too status	Nobi-Lincol Oral Powder Mfg. by M/s. Noble Pharma, Mirpur AJK (Reg. No. 079116)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	1 0
		000/- for correction in formulation, as per notification No.F.7-05-2021, before issuance of registration letter.
610.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
010.	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Linkzone-40 Powder
	Strength	Linkzone 40 i owder
	Composition	Each gram contains:
	Composition	Lincomycin (as Lincomycin Hydrochloride) (USP)400mg
	Diary No. Date of R& I & fee	Dy. No. 8076 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
		Antibiotic Dated 22-03-2025, RS. 30,000/- Dated 13-03-2025
	Pharmacological Group	
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled
	Me-too status	Lincosel 40 Powder Mfg. by M/s. Selmore Pharmaceuticals, Lahore (Reg. No. 089826)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	size of upto 1Kg.
611.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Linkzone-1.1 Water Soluble Powder
	Strength	Feeh 1000g contains:
	Composition	Each 1000g contains: Lincomycin HCl (USP)11g
	Di N D O O O O	
	Diary No. Date of R& I & fee	Dy. No. 8077 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Bio-Mycin Water soluble Powder Mfg. by M/s. Bio-Labs Pharmaceuticals, Islamabad (Reg. No. 082499)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	
		000/- for correction in formulation, as per notification No.F.7-05-2021, before issuance of registration letter.
	11/2012-D&A/DKAP dated U/-	03-2021, Defore Issuance of registration letter.

612.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
012.	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Linkzone-1.1 Premix
	Strength	
	Composition	Each 1000g contains: Lincomycin HCl (USP)110g
	Diary No. Date of R& I & fee	Dy. No. 8078 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Lincovet Premix Mfg. by M/s. Medi-vet, Lahore (Reg. No. 025397)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	2 9
	·	000/- for correction in formulation, as per notification No.F.7-
(12		05-2021, before issuance of registration letter.
613.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Linkzone-4.4 (Powder) Feed Premix
	Composition	Each 100g contains:
	Composition	Lincomycin HCl (USP)4.4g
	Diamy No. Data of D& I & foo	Dy. No. 8079 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Diary No. Date of R& I & fee Pharmacological Group	Antibiotic Solve dated 22-03-2023, RS. 30,000/- Dated 13-03-2023
	Type of Form	Form 5
		Innovator Specifications
	Finished product Specification	innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Lincos-P Oral Powder Mfg. by M/s. A&K Pharmaceuticals, Faisalabad (Reg. No. 049667)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	size of upto 1Kg.
		000/- for correction in formulation, as per notification No.F.7-
		05-2021, before issuance of registration letter.
614.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Linkozone-SS Oral Powder
	Strength	Early 100s contains:
	Composition	Each 100g contains: Lincomycin HCl (USP)5g
		Spectinomycin (BP)7.5g
		Spiramycinadipate (BP Vet)2.5g
		Bromhexine HCl (BP)0.5g
	Diary No. Date of R& I & fee	Dy. No. 8080 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic Services S
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	and the specifications
	- Specification	

		10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg:	
	Pack size & Demanded Price	Decontrolled	
	Me-too status	Speclinx Oral Powder Mfg. by M/s. Vantage Pharmaceuticals, Faisalabad (Reg. No. 081714)	
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022	
	Remarks of the Evaluator		
	Decision: Approved with pack		
		000/- for correction in formulation, as per notification No.F.7-05-2021, before issuance of registration letter.	
615.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.	
	Brand Name +Dosage Form +	Spectin-100 Powder	
	Strength		
	Composition	Each gram contains:	
		Lincomycin HCl (USP)33.3mg	
	Diama No. Data of D.C. I. C. for	Spectinomycin Sulphate (BP)66.7mg	
	Diary No. Date of R& I & fee	Dy. No. 8081 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic	
	Pharmacological Group	Form 5	
	Type of Form		
	Finished product Specification	Innovator Specifications	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled	
	Me-too status	Specnolin Powder Mfg. by M/s. Mediexcel Pharmaceuticals, Faisalabad (Reg. No. 031401)	
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022	
	Remarks of the Evaluator		
	Decision: Approved with pack size of upto 1Kg. Firm shall submit fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.		
616.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil	
	manufacturer / Applicant	Kamonke, Gujranwala.	
	Brand Name +Dosage Form +	Spectin-1000 Powder	
	Strength		
	Composition	Each gram contains:	
		Lincomycin (as HCl) (USP)335mg	
	Diama No. Data of D.C. I. C. for	Spectinomycin (as Sulphate) (BP)665mg Dy. No. 8082 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023	
	Diary No. Date of R& I & fee	Dy. No. 8082 dated 22-05-2025, Rs. 30,000/- Dated 15-05-2025 Antibiotic	
	Pharmacological Group	Form 5	
	Type of Form		
	Finished product Specification	Innovator Specifications	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled	
	Me-too status	L-Spec Powder Mfg. by M/s. Mallard Pharmaceuticals, Multan (Reg. No. 046626)	
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022	
	Remarks of the Evaluator		
	Decision: Approved with pack		
617.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil	
	manufacturer / Applicant	Kamonke, Gujranwala.	
	Brand Name +Dosage Form +	Tylozone-C Oral Powder	
	Strength Composition	Each 1000g contains:	
	Composition		
		L I VIOSIN L'ARTARATE (USP) L'UUG	
		Tylosin Tartarate (USP)100g Doxycycline HCl (USP)200g	

		[- 4
		Colistin Sulphate (BP)500 MIU Bromhexine HCl (BP)5g
	Diame No Date of DO 10 for	, , , -
	Diary No. Date of R& I & fee	Dy. No. 8083 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023 Antibiotic
	Pharmacological Group	
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Tycobar-D Oral Powder Mfg. by M/s. Baariq Pharmaceuticals, Lahore (Reg. No. 071099)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	size of upto 1Kg.
		000/- for correction in formulation, as per notification No.F.7-
		05-2021, before issuance of registration letter.
618.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Tylozone 10 Oral Powder
	Strength	
	Composition	Each 1000g contains:
		Tylosin Tartarate (USP)100g
		Doxycycline HCl (USP)200g
		Colistin Sulphate (BP)480 MIU
	D: N D CD0 V 0 C	Bromhexine HCl (BP)5g
	Diary No. Date of R& I & fee	Dy. No. 8084 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Maxdox Water Soluble Powder Mfg. by M/s. Baariq Pharmaceuticals, Lahore (Reg. No. 087144)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Approved with pack	size of upto 1Kg.
		000/- for correction in formulation, as per notification No.F.7-
		05-2021, before issuance of registration letter.
619.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Tylozone Oral Powder
	Strength	E 1 1000
	Composition	Each 1000g contains:
		Tylosin Tartarate (USP)100g
		Doxycycline HCl (USP)200g Colistin Sulphate (BP)50g
		Bromhexine HCl (BP)5g
	Diary No. Date of R& I & fee	Dy. No. 8085 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic Dated 22-03-2023, RS. 50,000/- Dated 10-03-2023
		Form 5
	Type of Form	
	Finished product	Innovator Specifications
	Specification	10 20 50 100 250 500 11 101 1251 251
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
		

		CD Dags Out Davider Mfs. by M/s. Zalrfas Dharmacauticals
i '	Me-too status	CD Raas Oral Powder Mfg. by M/s. Zakfas Pharmaceuticals, Multan (Reg. No. 057072)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	Divid issued on 10-02-2023, East hispection. 22-12-2022
	Decision: Approved with pack	size of unto 1Kg.
		000/- for correction in formulation, as per notification No.F.7-
		05-2021, before issuance of registration letter.
620.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Tylozone-40 Oral Powder
	Strength	
	Composition	Each 100g contains:
		Tylosin Tartarate (USP)20g
ļ		Doxycycline HCl (USP)40g
		Colistin Sulphate (BP)10g
	Diama Na Data af D 0 I 0 for	Bromhexine HCl (BP)2g
	Diary No. Date of R& I & fee	Dy. No. 8086 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic
	Pharmacological Group	
	Type of Form	Form 5
	Finished product	Innovator Specifications
ļ	Specification	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	MultiDox Oral Powder Mfg. by M/s. Hawk Bio Pharmaceuticals, Islamabad (Reg. No. 078395)
ļ	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
ļ	Decision: Approved with pack size of upto 1Kg.	
	-	000/- for correction in formulation, as per notification No.F.7-
(21	Name and address of	05-2021, before issuance of registration letter.
621.	Name and address of	
		M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	manufacturer / Applicant Brand Name +Dosage Form +	
	manufacturer / Applicant Brand Name +Dosage Form + Strength	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder
	manufacturer / Applicant Brand Name +Dosage Form +	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains:
	manufacturer / Applicant Brand Name +Dosage Form + Strength	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic Form 5
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic Form 5 Innovator Specifications 10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg:
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic Form 5 Innovator Specifications 10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic Form 5 Innovator Specifications 10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled SB Tiaclor Oral Powder Mfg. by M/s. SB Pharma, Islamabad
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic Form 5 Innovator Specifications 10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled SB Tiaclor Oral Powder Mfg. by M/s. SB Pharma, Islamabad (Reg. No. 048223)
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic Form 5 Innovator Specifications 10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled SB Tiaclor Oral Powder Mfg. by M/s. SB Pharma, Islamabad
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic Form 5 Innovator Specifications 10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled SB Tiaclor Oral Powder Mfg. by M/s. SB Pharma, Islamabad (Reg. No. 048223) DML Issued on 16-02-2023, Last inspection: 22-12-2022
622.	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic Form 5 Innovator Specifications 10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled SB Tiaclor Oral Powder Mfg. by M/s. SB Pharma, Islamabad (Reg. No. 048223) DML Issued on 16-02-2023, Last inspection: 22-12-2022
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack states	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic Form 5 Innovator Specifications 10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled SB Tiaclor Oral Powder Mfg. by M/s. SB Pharma, Islamabad (Reg. No. 048223) DML Issued on 16-02-2023, Last inspection: 22-12-2022
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack states Name and address of	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic Form 5 Innovator Specifications 10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled SB Tiaclor Oral Powder Mfg. by M/s. SB Pharma, Islamabad (Reg. No. 048223) DML Issued on 16-02-2023, Last inspection: 22-12-2022 size of upto 1Kg. M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack state Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic Form 5 Innovator Specifications 10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled SB Tiaclor Oral Powder Mfg. by M/s. SB Pharma, Islamabad (Reg. No. 048223) DML Issued on 16-02-2023, Last inspection: 22-12-2022 size of upto 1Kg. M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala. Fosfozone Dry Powder
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack state Name and address of manufacturer / Applicant Brand Name +Dosage Form +	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic Form 5 Innovator Specifications 10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled SB Tiaclor Oral Powder Mfg. by M/s. SB Pharma, Islamabad (Reg. No. 048223) DML Issued on 16-02-2023, Last inspection: 22-12-2022 size of upto 1Kg. M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala. Fosfozone Dry Powder Each gram contains:
	manufacturer / Applicant Brand Name +Dosage Form + Strength Composition Diary No. Date of R& I & fee Pharmacological Group Type of Form Finished product Specification Pack size & Demanded Price Me-too status GMP status Remarks of the Evaluator Decision: Approved with pack state Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	Kamonke, Gujranwala. Tiazone-10 Oral Soluble Powder Each 100g contains: Tiamulin Hydrogen Fumarate (USP)10g Chlortetracycline Hydrochloride (USP)30g Dy. No. 8087 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023 Antibiotic Form 5 Innovator Specifications 10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg: Decontrolled SB Tiaclor Oral Powder Mfg. by M/s. SB Pharma, Islamabad (Reg. No. 048223) DML Issued on 16-02-2023, Last inspection: 22-12-2022 size of upto 1Kg. M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala. Fosfozone Dry Powder

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
		10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg:
	Pack size & Demanded Price	Decontrolled
	Me-too status	Cannot be confirmed.
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	i. Me-too status required for applied formulation.
	Decision: Deferred for confirms	
623.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Amazone-10 Oral Powder
	Strength	
	Composition	Each 1000g contains:
		Amantadine HCl (BP)100g
	Diary No. Date of R& I & fee	Dy. No. 8089 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
		10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg:
	Pack size & Demanded Price	Decontrolled
	Markanakatan	Rescue-100 Oral Powder Mfg. by M/s. Baariq Pharmaceuticals,
	Me-too status	Lahore (Reg. No. 079812)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
		f formulation by expert working group on veterinary drugs.
624.	Name and address of	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil
	manufacturer / Applicant	Kamonke, Gujranwala.
	Brand Name +Dosage Form +	Amazone-98 Oral Powder
	Strength	7 1 100
	Composition	Each 100g contains:
		Amantadine HCl (BP)98g
	Diary No. Date of R& I & fee	Dy. No. 8090 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product	Innovator Specifications
	Specification	
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Amadine-98 Oral Powder Mfg. by M/s. Aptly Pharmaceuticals, Faisalabad (Reg. No. 093841)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of	f formulation by expert working group on veterinary drugs.

$Case\ No.\ 02-Routine\ registration\ application\ of\ Veterinary\ Drugs\ on\ Form-5\ (Local).$

625.	Name and address of	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City
	manufacturer / Applicant	Sahainwala, Faisalabad.
	Brand Name +Dosage Form +	Kryptin Oral Liquid
	Strength	

	Composition	Each ml contains:
		Enrofloxacin (EP)75mg
		Sulphamethoxypyrizadine (EP)75mg
		Sulphamethazine (USP)50mg
		Trimethoprim (EP)25mg
	Diary No. Date of R& I & fee	Dy. No. 1192 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	In-house specifications
	Specification	
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1L, 2.5L, 5L : Decontrolled
	1 ack size & Demanded 1 fice	Cina TS Oral Suspension Mfg. by M/s. Vety care
	Me-too status	Pharmaceuticals, Islamabad (Reg. No. 031456)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished
	Desigion: Defermed for review of	product. f formulation by expert working group on vetering we drugg
626.	Name and address of	f formulation by expert working group on veterinary drugs.
U 2 U.	manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Age-Kryp Oral Liquid
	Composition	Each 100ml contains:
	Composition	Enrofloxacin (EP)10mg
		Aminophylline (BP)4g
		Guaifenesin (USP)10g
	Diary No. Date of R& I & fee	Dy. No. 1196 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic/Expectorant/Bronchodilator
		Form 5
	Type of Form	
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1L, 2.5L, 5L : Decontrolled
	Me-too status	EG Enro plus liquid Mfg. by M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 074099)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished
	Remarks of the Evaluator	product.
	Decision: Deferred for review of	f formulation by expert working group on veterinary drugs.
627.	Name and address of	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City
	manufacturer / Applicant	Sahainwala, Faisalabad.
	Brand Name +Dosage Form +	KP-Dotylo C Oral Powder
	Strength	Feeh 1000g contains:
	Composition	Each 1000g contains: Tylosin Tartarate (EP)100g
		Doxycyline (BP)200g
	Diary No. Data of D % I % for	Colistin Sulphate (BP)30g
	Diary No. Date of R& I & fee	Dy. No. 1168 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021 Antibiotic
	Pharmacological Group	
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	•	50g, 100g, 250g, 500g, 450g, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg,
	Pack size & Demanded Price	20Kg, 25Kg : Decontrolled
	Me-too status	Doxi-Tol Powder Mfg. by M/s. Leads Pharma, Islamabad (Reg. No. 057053)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.

	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.
		submit fee of Rs. 30,000/- for correction in formulation, as per A/DRAP dated 07-05-2021, before issuance of registration
628.	Name and address of manufacturer / Applicant Brand Name +Dosage Form + Strength	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad. KP-Bromo Oral Liquid
	Composition	Each 100ml contains: Bromhexine HCl (BP)5g
	Diary No. Date of R& I & fee Pharmacological Group	Dy. No. 1220 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021 Mucolytic
	Type of Form	Form 5
	Finished product Specification	In-house specifications
		501 1001 2501 4501 5001 11 2 51 51 . December 11 d
	Pack size & Demanded Price Me-too status	50ml, 100ml, 250ml, 450ml, 500ml, 1L, 2.5L, 5L: Decontrolled Bromo Shell Liquid Mfg. by M/s. Inshal Pharmaceuticals,
	CMP status	Islamabad (Reg. No. 075762) Inspection for issuance of DML conducted on 12-20-2020.
	GMP status Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.
	submit fee of Rs. 7,500/- for conotification No.F.7-11/2012-B& letter	rator's specifications and pack size of upto 1L. The firm shall prrection/pre-approval change in product specifications as per A/DRAP dated 07-05-2021, before issuance of registration
629.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	KP-Colineocin Oral Powder
	Composition	Each 1000g contains: Chlortetracycline (BP)80g Neomycin Sulphate (BP)70g Colistin Sulphate (BP)4g Bromhexine HCl (BP)5g
	Diary No. Date of R& I & fee	Dy. No. 1196 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50g, 100g, 200g, 250g, 450g, 500g, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25K : Decontrolled
	Me-too status	Q.NCC 200 Powder Mfg. by M/s. Mallard Pharmaceuticals, Multan (Reg. No. 079222)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.
	submit fee of Rs. 30,000/- for co	ator's specifications and pack size of upto 1Kg. Firm shall rrection in formulation, as per notification No.F.7-11/2012-before issuance of registration letter.
630.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	KP-Resto D Oral Powder

		,
	Composition	Each 1000g contains:
		Tylosin Tartarate (EP)100g
		Doxycycline HCl (BP)200g
		Colistin Sulphate (BP) 500 MIU
		Bromhexine (EP)5g
		Phenylbutazone (USP)12g
	Diary No. Date of R& I & fee	Dy. No. 1181 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	In-house specifications
	Specification	
	Pack size & Demanded Price	50g, 100g, 250g, 450g, 500g, 1Kg, 2.5Kg, 5Kg : Decontrolled
	1 dek size & Demanded i nec	Resco Powder Mfg. by M/s. Leads Pharmaceuticals, Islamabad
	Me-too status	(Reg. No. 044965)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished
	Remarks of the Evaluator	product.
		ii. Firm has not provided the conversion of Colistin Suphate
		from MIU to grams.
	Decision: Deferred for review of	f formulation by expert working group on veterinary drugs.
631.	Name and address of	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City
051.	manufacturer / Applicant	Sahainwala, Faisalabad.
	Brand Name +Dosage Form +	KP-Fosco Oral Powder
	Strength	Ki -i osco Otar i owaci
	Composition	Each 100g contains:
	Composition	Fosfomycin Calcium (EP)20g
		Fructose (EP)18g
		Tylosin Tartarate (EP)10g
		Sodium Phosphate (BP)15g
		Magnesium Sulphate (USP)10g
	Diary No. Date of R& I & fee	Dy. No. 1179 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	In-house specifications
		in-nouse specifications
	Specification	50 - 100 - 250 - 450 - 500 - 1V - 25V - 5V - Decentralled
	Pack size & Demanded Price	50g, 100g, 250g, 450g, 500g, 1Kg, 2.5Kg, 5Kg : Decontrolled
	Me-too status	Fosfotyl Powder Mfg. by M/s. Leads Pharmaceuticals, Islamabad
		(Reg. No. 078240)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished
		product.
		on of drug product analytical procedure along with evidence of
(22	requisite testing facility, for the	
632.	Name and address of	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City
	manufacturer / Applicant	Sahainwala, Faisalabad.
	Brand Name +Dosage Form +	T Fluton D Oral Powder
	Strength	
	Composition	Each Kg contains:
		Tylosin Tartarate (EP)10%
	Diame No. D. (CDO 10 C	Doxycycline (BP)20%
	Diary No. Date of R& I & fee	Dy. No. 1215 dated 08-01-2021, Rs. 20,000/- Dated 07-01- 2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	In-house specifications
	Specification	
		

	Pack size & Demanded Price	50g, 100g, 250g, 450g, 500g, 1Kg, 2.5Kg, 5Kg : Decontrolled
	Me-too status	Biodox-T Powder Mfg. by M/s. Bio Labs, Islamabad (Reg. No. 028541)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.
		000/- for correction in formulation, as per notification No.F.7- 05-2021, before issuance of registration letter.
633.	Name and address of	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City
	manufacturer / Applicant	Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Strepto-Kyp Oral Powder
	Composition	Each 1000g contains:
		Tylosin Tartarate (EP)10%
		Doxycycline Hyclate (BP)20%
		Colistin Sulphate (BP)450 MIU
		Bromhexine HCl (EP)0.5%
		Streptomycin Sulphate (EP)3.6%
	Diary No. Date of R& I & fee	Dy. No. 1203- dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	In-house specifications
	Specification	
	Pack size & Demanded Price	50g, 100g, 200g, 250g, 450g, 500g, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg: Decontrolled
	Me-too status	Biodox-T Powder Mfg. by M/s. Nobel Pharma Mirpur, AJ&K (Reg. No. 075609)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.ii. Firm has not provided the conversion of Colistin Suphate
		from MIU to grams or %.
	Decision: Deferred for review of	f formulation by expert working group on veterinary drugs.
634.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	KP T.S Oral (Antibiotic Oral Liquid)
	Composition	Each 1000ml contains:
		Tylosin Tartarate (EP)50g
		Sulphamethoxypyridazine (EP)50g
		Trimethoprim (EP)10g
		Bromhexine HCl (EP)5g
	Diary No. Date of R& I & fee	Dy. No. 1182 - dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1L, 2.5L, 5L : Decontrolled
	Me-too status	Compli Plus Liquid Mfg. by M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 073998)
	GMP status	Inspection for issuance of DML conducted on 12-10-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished
	Tomain of the Dividuoi	product.

		ator's specifications and pack size of upto 1L. Firm shall submit in formulation, as per notification No.F.7-11/2012-B&A/DRAP ce of registration letter.
635.	Name and address of manufacturer / Applicant	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road, Sheikhupura.
	Brand Name +Dosage Form + Strength	Bromocol-E Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin as HCl10g Colistin Sulphate5 MIU Bromhexine0.50%
	Diary No. Date of R& I & fee	Dy. No. 1792 - dated 13-01-2021, Rs. 20,000/- Dated 23-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Compli Plus Liquid Mfg. by M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 073998)
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
636.		 i. Valid Form-5 with signature of authorised person/applicant is required. ii. Valid copy of DML is required iii. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required. iv. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. v. Firm has claimed Manufacturers specifications for finished product. vi. Firm has not provided the conversion of Colistin Suphate from MIU to grams. eferred for the submission of Form 5 signed by the authorized distration as per notification No.F.7-11/2012-B&A/DRAP dated M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road, Sheikhupura. Oxyfloro-N Oral Powder Each Kg contains: Neomycin Sulphate (BP)150g Florfenicol100g
	Diamy No. Data of D.O. L.O. S.	Oxytertacyclin HCl (BP)300
	Diary No. Date of R& I & fee	Dy. No. 1788 - dated 13-01-2021, Rs. 20,000/- Dated 06-01-2021 Antibiotic
	Pharmacological Group	Form 5
	Type of Form	Manufacturer specifications
	Finished product	Manufacturer specifications
	Specification Pack size & Demanded Price	100g, 200g, 250g, 500g, 1000g : Decontrolled
	Me-too status	Neoxflor Oral Powder Mfg. by M/s. Baariq Pharmaceuticals,
	GMP status	Lahore (Reg. No. 088638) GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
	Remarks of the Evaluator	i. Valid Form-5 with signature of authorised person/applicant is required.

		ii. Valid copy of DML is required
		iii. Latest GMP certificate/inspection report of M/s Intervac
		(Pvt.) Ltd., Sheikhupura conducted within last 03 years is
		required.
		iv. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd.,
		Sheikhupura is required.
		v. Firm has claimed Manufacturers specifications for
		finished product.
	Decision: Registration Board de	eferred for the submission of Form 5 signed by the authorized
		gistration as per notification No.F.7-11/2012-B&A/DRAP dated
	07-05-2021.	addition as per nomicularity 11/2012 Desir Dian autou
637.	Name and address of	M/a Intervae (Dut.) Ltd. 19 Vm Labora Chailthunura Dood
057.		M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road,
	manufacturer / Applicant	Sheikhupura.
	Brand Name +Dosage Form +	Cocxifas Super Powder
	Strength	
	Composition	Each gram contains:
	r	Amprolium HCl166mg
		Sulphaquinoxaline166mg
		Colistin Sulphate50000 IU
		Vitamin A50000 IU
		Vitamin K5mg
	Diary No. Date of R& I & fee	Dy. No. 1785 - dated 13-01-2021, Rs. 20,000/- Dated 29-12-2020
	Pharmacological Group	Antibiotic & Multivitamins
		Form 5
	Type of Form	
	Finished product	Manufacturer specifications
	Specification	
	Pack size & Demanded Price	100g, 200g, 250g, 500g, 1000g : Decontrolled
		Me-too status cannot be confirmed.
	Me-too status	
	GMP status	GMP certificate not provided. Last inspection for DML renewal
		conducted on 19-06-2019.
	Remarks of the Evaluator	i. Me-too status cannot be confirmed.
		ii. Valid Form-5 with signature of authorised
		person/applicant is required.
		iii. Valid copy of DML is required
		iv. Latest GMP certificate/inspection report of M/s Intervac
		(Pvt.) Ltd., Sheikhupura conducted within last 03 years is
		required.
		v. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd.,
		Sheikhupura is required.
		vi. Firm has claimed Manufacturers specifications for
		finished product.
		vii. Firm has not provided the conversion of Colistin Suphate
		from MIU to grams.
	Decision: Registration Board de	eferred for the submission of Form 5 signed by the authorized
	person along with full fee of reg	gistration as per notification No.F.7-11/2012-B&A/DRAP dated
	07-05-2021.	
638.	Name and address of	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road,
0000	manufacturer / Applicant	Sheikhupura.
		Amidiofas Plus Powder
	Brand Name +Dosage Form +	Amidioras Pius Powder
	Strength	
	Composition	Each Kg contains:
		Amprolium200mg
		Furaltadone200mg
		Vitamin A4000000 IU
		Vitamin D32000000 IU
	1	1 Vitamin I/2 10-
		Vitamin K310g Dy. No. 1790 - dated 14-01-2021, Rs. 20,000/- Dated 06-01-2021

	Pharmacological Group	Antibiotic, Multivitamins
	Type of Form	Form 5
	Finished product	Manufacturer specifications
	Specification	
	Pack size & Demanded Price	100g, 200g, 250g, 500g, 1000g : Decontrolled
	Me-too status	Me-too status cannot be confirmed.)
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
		 i. Me-too status cannot be confirmed. ii. Valid Form-5 with signature of authorised person/applicant is required. iii. Valid copy of DML is required iv. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required. v. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. vi. Firm has claimed Manufacturers specifications for finished product. eferred for the submission of Form 5 signed by the authorized eistration as per notification No.F.7-11/2012-B&A/DRAP dated
(20)	07-05-2021.	
639.	Name and address of manufacturer / Applicant	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road, Sheikhupura.
	Brand Name +Dosage Form +	Bensel Injection
	Strength	Benser injection
	Composition	Each ml contains:
		Lincomycin (as HCl)40mg
		Spectnomycin (as HCl)80mg
		Benzyl Alcohol9mg
	Diary No. Date of R& I & fee	Dy. No. 1789 - dated 14-01-2021, Rs. 20,000/- Dated 29-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml : Decontrolled
	Me-too status	LSA Injection Mfg. by M/s. Leads Pharma, Islamabad (Reg. No. 063724)
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
		 i. Valid Form-5 with signature of authorised person/applicant is required. ii. Valid copy of DML is required iii. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required. iv. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. v. Firm has claimed Manufacturers specifications for finished product. eferred for the submission of Form 5 signed by the authorized distration as per notification No.F.7-11/2012-B&A/DRAP dated
640.	Name and address of	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road,
0-10.	manufacturer / Applicant	Sheikhupura.
<u> </u>	1	· r · · · ·

	Brand Name +Dosage Form + Strength	Intermox-G Injection
	Composition	Each ml contains: Amoxicillin Trihydrate eq. to Amoxicillin (BP)150mg Gentamycin Sulphate eq to Gentamycin (BP)40mg
	Diary No. Date of R& I & fee	Dy. No. 1791 - dated 14-01-2021, Rs. 20,000/- Dated 23-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Manufacturer specifications
	Specification	
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Me-too status cannot be confirmed.
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
	Remarks of the Evaluator	 i. Me-too status cannot be confirmed. ii. Valid Form-5 with signature of authorised person/applicant is required. iii. Valid copy of DML is required iv. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required. v. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required.
	Decision: Registration Board de	vi. Firm has claimed Manufacturers specifications for finished product. eferred for the submission of Form 5 signed by the authorized
	07-05-2021.	istration as per notification No.F.7-11/2012-B&A/DRAP dated
641.	Name and address of	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road,
	manufacturer / Applicant	Sheikhupura.
	Brand Name +Dosage Form + Strength	Multimax Injection
	Composition	Each 100ml contains:
	Composition	L-CaR&Itne (USP)500mg
		Pyridoxine Hydrochloride (BP)15mg
		Cyanocobalamin (BP)3mg
		DL-Acetyl methionine (MS)2000mg
		L-Arginine (BP)240mg
		L-Citruline (MS)120mg
		Glycine (BP)150mg
		Aspartic Acid (BP)150mg
		Fructose (BP)5000mg
		Thioctic Acid (BP)20mg
		L-OR&Ithine (MS)120mg L-Lysine (USP)50mg
		Taurine (USP)150mg
		Glutamic Acid (BP)150mg
		Sorbitol (BP) 8000mg
	Diary No. Date of R& I & fee	Dy. No. 1786 - dated 14-01-2021, Rs. 20,000/- Dated 29-12-2020
	Pharmacological Group	Amino Acids and Multivitamins
	Type of Form	Form 5
	Finished product	Manufacturer specifications
	Specification	•
	Pack size & Demanded Price	250ml : Decontrolled
	Me-too status	Multimino-V Injection Mfg. by M/s. Selmore Pharmaceuticals, Lahore (Reg. No. 058712)

	CMD status	CMD contificate not provided. Lost inspection for DML renewed
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
	Remarks of the Evaluator	 i. Valid Form-5 with signature of authorised person/applicant is required. ii. Valid copy of DML is required iii. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is
		required. iv. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd.,
		Sheikhupura is required. v. Firm has claimed Manufacturers specifications finished product.
	person along with full fee of reg	ferred for the submission of Form 5 signed by the authorized istration as per notification No.F.7-11/2012-B&A/DRAP dated
	07-05-2021.	
642.	Name and address of manufacturer / Applicant	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road, Sheikhupura.
	Brand Name +Dosage Form + Strength	Gentafas 15% Injection
	Composition	Each ml contains: Gentamycin Sulphate150mg
	Diary No. Date of R& I & fee	Dy. No. 1784 - dated 14-01-2021, Rs. 20,000/- Dated 08-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Me-too status cannot be confirmed.
	GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
	Remarks of the Evaluator	 i. Me-too status cannot be confirmed. ii. Valid Form-5 with signature of authorised person/applicant is required. iii. Valid copy of DML is required
		iv. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required.
		v. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. vi. Firm has claimed Manufacturers specifications for
		finished product.
		eferred for the submission of Form 5 signed by the authorized
	07-05-2021.	istration as per notification No.F.7-11/2012-B&A/DRAP dated
643.	Name and address of	M/s. Intervac (Pvt.) Ltd., 18-Km Lahore Sheikhupura Road,
	manufacturer / Applicant	Sheikhupura.
	Brand Name +Dosage Form + Strength	Gentafas 20% Injection
	Composition	Each ml contains: Gentamycin as Sulphate (BP)200mg
	Diary No. Date of R& I & fee	Dy. No. 1787 - dated 14-01-2021, Rs. 20,000/- Dated 08-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product	Manufacturer specifications
	Specification	
	Pack size & Demanded Price	100ml : Decontrolled
	rack size & Demanded Price	TOOMI . Decontrolled

Me-too status	Gentabar-20 Injection Mfg. by M/s. Baariq Pharmaceuticals, Lahore (Reg. No. 087121)
GMP status	GMP certificate not provided. Last inspection for DML renewal conducted on 19-06-2019.
Remarks of the Evaluator	 i. Valid Form-5 with signature of authorised person/applicant is required. ii. Valid copy of DML is required iii. Latest GMP certificate/inspection report of M/s Intervac (Pvt.) Ltd., Sheikhupura conducted within last 03 years is required.
	 iv. Section Approval Letter of M/s. M/s Intervac (Pvt.) Ltd., Sheikhupura is required. v. Firm has claimed Manufacturers specifications for finished product.

Decision: Registration Board deferred for the submission of Form 5 signed by the authorized person along with full fee of registration as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Case no. 01 Registration applications for local manufacturing of (Human) drugs (Form 5)

a.	New cases	

	a. New cases	
644.	Name and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Tablet section (General)
	Brand Name +Dosage Form +	OLAM tablet 20/5mg
	Strength	
	Composition	Each film coated tablet contains:
		Amlodipine20mg
		Olmesartan Medoxomil5mg
	Diary No. Date of R& I & fee	Dy No. 14588 dated 07-03-2019 Fee paid PKR 20,000/- vide
		Deposit Slip No. 0789191 dated 07-03-2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel
		blockers
		ATC Code C09DB02
	Type of Form	Form 5
	Finished Product Specification	Not mentioned by applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Not provided
	Reference Regulatory	
	Authorities.	N . C . 1
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period
		of last three years is required.
		 Finished product specifications are required.
		• Evidence of approval of applied product in reference
		regulatory authority is required.
		Evidence of applied formulation/drug already approved
		by DRAP (generic / me-too status) along with
		registration number, brand name and name of firm is
		required.
	Decision: Deferred for following:	
	• Evidence of approva	
	1	ch were adopted by Registration Board in its 275th meeting)
		n as available in reference regulatory authority, along with
		ification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.
		eport conducted within last three years.
	 Submission of finished presented in the state of the stat	•
		nulation/drug already approved by DRAP (generic / me-too
	1	ation number, brand name and name of firm.
(15		,
645.		M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Tablet section (General)
	Brand Name +Dosage Form +	CARDIMAX 35mg tablet
	Strength	
	Composition	Each film coated modified release tablet contains:
		Trimetazine dihydrochloride 35mg
	Diary No. Date of R& I & fee	Dy No. 16728 dated 07-03-2019 Fee paid PKR 20,000/- vide
		Deposit Slip No. 0792370 dated 06-03-2019.
	Pharmacological Group	Other cardiac preparations
	<i>S</i> r	ATC Code C01EB15 (Trimetazidine)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed Innovator's Specifications; Trimetazidine
		hydrochloride tablets monograph is available in JP
		nj alo omoliae moleae monograph is a tanaole in si

	Pack size & Demanded Price	As per SRO
	Approval status of product in	Trimetazidine biogaran 35 mg, film-coated tablet with modified
		6
	Reference Regulatory	release
	Authorities.	ANSM approved
	Me-too status	Ofimta MR tablet 35mg
		High-Q Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	 Latest GMP inspection report conducted within a period
		of last three years is required.
		• Change of name from Trimetazine to Trimetazidine is
		required on cover letter and other points in Form 5 along
	!	with requisite fee.
	!	^
		• Change in specifications from innovator's specifications to JP is required along with requisite fee.
	Decision: Deferred for following:	:
		eport conducted within last three years.
		rimetazine to Trimetazidine on cover letter and other points in
		ng with prescribed fee as per notification No.F.7-11/2012-
	B&A/DRAP dated 13-07-	
	 Change in specifications 	from innovator's specifications to JP along with prescribed fee
	as per notification No.F.7	7-11/2012- B&A/DRAP dated 13-07-2021.
646.	Name and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Tablet section (General)
	Brand Name +Dosage Form +	BISOCAR tablet 5mg
	Strength	Discourt moter sing
	Composition	Each film coated tablet contains:
	Composition	Bisoprolol fumarate 5mg
	Diam No Data of De Le for	
	Diary No. Date of R& I & fee	Dy No. 14594 dated 07-03-2019 Fee paid PKR 20,000/- vide
		Deposit Slip No. 0792384 dated 06-03-2019.
	Pharmacological Group	Beta blocking agents, selective
		ATC Code C07AB07
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Bisoprolol fumarate 5 mg film-coated tablets
	Reference Regulatory	Marketing Authorization Holder:
	Authorities.	Generics [UK] Limited t/a Mylan, UK.
		MHRA Approved
	Me-too status	Saibiso Tablet by Saibins Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	•
	Remarks of the Evaluator .	Latest GMP inspection report conducted within a period of last three years is required.
		of last three years is required.
		on of latest GMP inspection report conducted within last three
CAF	years.	M/s Line Discourse discharge Nr. 2 Co. Nr. C. 7 Nr.: 1
647.	Name and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Tablet section (General)
	Brand Name +Dosage Form +	OFLO tablet 200mg
	Strength	
	Composition	Each film coated tablet contains:
	-	Ofloxacin200mg
	Diary No. Date of R& I & fee	Dy No. 14575 dated 07-03-2019 Fee paid PKR 20,000/- vide
		Deposit Slip No. 0789178 dated 07-03-2019.
	Pharmacological Group	Fluoroquinolones
	i narmacological Group	•
	T	ATC Code J01MA01
<u> </u>	Type of Form	Form 5

	Finished Product Specification Pack size & Demanded Price Approval status of product in Reference Regulatory Authorities. Me-too status GMP status Remarks of the Evaluator ^{xxiii} .	USP As per SRO Ofloxacin 200mg film coated tablets Company: Teva UK Ltd MHRA Approved Ofloper 200mg Tablet Quaper Pvt Ltd
_	Approval status of product in Reference Regulatory Authorities. Me-too status GMP status	Ofloxacin 200mg film coated tablets Company: Teva UK Ltd MHRA Approved Ofloper 200mg Tablet Quaper Pvt Ltd
_	Reference Regulatory Authorities. Me-too status GMP status	Company: Teva UK Ltd MHRA Approved Ofloper 200mg Tablet Quaper Pvt Ltd
-	Authorities. Me-too status GMP status	MHRA Approved Ofloper 200mg Tablet Quaper Pvt Ltd
_	Me-too status GMP status	Ofloper 200mg Tablet Quaper Pvt Ltd
_	GMP status	Quaper Pvt Ltd
		Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator	Latest GMP inspection report conducted within a period
_	Remarks of the Evaluator .	of last three years is required.
	Decision: Deferred for submission	on of latest GMP inspection report conducted within last three
	years.	in of facest Givir inspection report conducted within fast time
	Name and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
	T.F.	Capsule section (General)
	Brand Name +Dosage Form +	VENFAX- SR Capsules 75mg
	Strength	
	Composition	Each extended release capsule contains:
	T	Extended release pellets of Venlafaxine Hydrochloride
		equivalent to Venlafaxine75mg
	Diary No. Date of R& I & fee	Dy No. 14598 dated 07-03-2019 Fee paid PKR 20,000/- vide
		Deposit Slip No. 0792388 dated 06-03-2019.
	Pharmacological Group	Other antidepressants
		ATC Code N06AX16
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
l ==	Approval status of product in	Alventa XL 75 mg prolonged-release capsules, hard
	Reference Regulatory	MHRA Approved
	Authorities.	Militarrippioved
I	Me-too status	Venwell XR 75mg Capsule
	Tite too status	FYNK Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
-	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period
		of last three years is required.
		• Source of pellets is not provided; source of pellets along
		with GMP certificate of that source, stability study of
		three batches of pellets and certificate of analysis of
		pellets are required. In case of imported pellets, requisite
		fee is also required.
	Decision: Deferred for following:	
		with stability studies data, GMP certificate of supplier and
	differential fee in case of	
	 Latest GMP inspection re 	eport conducted within last three years.
		M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		`
	· ·	VENFAX- SR Capsules 37.5mg
	Strength	
	Composition	Each extended release capsule contains:
		Extended release pellets of Venlafaxine Hydrochloride
_	Composition	Extended release pellets of Venlafaxine Hydrochloride equivalent to Venlafaxine37.5mg
		Extended release pellets of Venlafaxine Hydrochloride equivalent to Venlafaxine37.5mg Dy No. 14597 dated 07-03-2019 Fee paid PKR 20,000/- vide
	Composition	Extended release pellets of Venlafaxine Hydrochloride equivalent to Venlafaxine37.5mg
_	Composition	Extended release pellets of Venlafaxine Hydrochloride equivalent to Venlafaxine37.5mg Dy No. 14597 dated 07-03-2019 Fee paid PKR 20,000/- vide
_	Composition Diary No. Date of R& I & fee	Extended release pellets of Venlafaxine Hydrochloride equivalent to Venlafaxine37.5mg Dy No. 14597 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792387 dated 06-03-2019.
	differential fee in case ofLatest GMP inspection re	import of pellets. eport conducted within last three years. M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, Nation Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General) VENFAX- SR Capsules 37.5mg

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Alventa XL 37.5 mg prolonged-release capsules, hard
	Reference Regulatory	MHRA Approved
	Authorities.	**
	Me-too status	Fix-Zar 37.5mg XR Capsule
		Invictus Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	 Latest GMP inspection report conducted within a period of last three years is required.
		 Source of pellets is not provided; source of pellets along with GMP certificate of that source, stability study of
		three batches of pellets and certificate of analysis of
		pellets are required. In case of imported pellets, requisite fee is also required.
	Decision: Deferred for following	•
		with stability studies data, GMP certificate of supplier and
	differential fee in case of	
		eport conducted within last three years.
650.	Name and address of	, , , , , , , , , , , , , , , , , , , ,
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
	D IN D E	Tablet section (General)
	Brand Name +Dosage Form + Strength	BISOCAR tablet 2.5mg
	Composition	Each film coated tablet contains:
		Bisoprolol fumarate2.5mg
	Diary No. Date of R& I & fee	Dy No. 16726 dated 07-03-2019 Fee paid PKR 20,000/- vide
	Pharmacological Group	Deposit Slip No. 0792366 dated 06-03-2019. Beta blocking agents, selective
	Filarinacological Group	ATC Code C07AB07
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Bisoprolol fumarate 2.5 mg film-coated tablets
	Reference Regulatory	PL 04569/1255
	Authorities.	Marketing Authorization Holder:
		Generics [UK] Limited t/a Mylan, UK.
	76	MHRA Approved
	Me-too status	Saibiso Tablet by Saibins Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period of last three years is required.
	Dacision: Deferred for submission	of last three years is required. on of latest GMP inspection report conducted within last three
	years.	on or racest Givir inspection report conducted within last tillee
651.	Name and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Tablet section (General)
	Brand Name +Dosage Form + Strength	AVENT 16mg tablet
	Composition	Each film coated tablet contains:
		Candesartan Cilexetil 16mg
	Diary No. Date of R& I & fee	Dy No. 14605 dated 07-03-2019 Fee paid PKR 20,000/- vide
	Dharmanala sinal Crass	Deposit Slip No. 0792395 dated 06-03-2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain ATC Code C09CA06
	Type of Form	Form 5
	Finished Product Specification	USP

	D1 0 D1-1 D	A CDO
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Candesartan Cilexetil 16 mg Tablets - PL 35084/0002-9;
	Reference Regulatory	MHRA Approved (for uncoated tablet).
	Authorities.	
	Me-too status	Cansaar 8mg Tablet (uncoated)
		M/s Pharmatec Pakistan Karachi
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	 Latest GMP inspection report conducted within a period of last three years is required.
		Applied product is film coated tablet. Evidence of product approved in reference regulatory authority is of uncoated tablets. Approval of film coated tablet in reference regulatory authority or change of formulation from film coated to uncoated tablet along with requisite fee is required.
	regulatory authority, al- B&A/DRAP dated 13-07	from film coated to uncoated tablet as available in reference ong with prescribed fee as per notification No.F.7-11/2012-2021.
	 Latest GMP inspection r 	eport conducted within last three years.
652.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	DESVEN tablet 50mg
	Composition	Each film coated tablet contains: Desvenlafaxine50mg
	Diary No. Date of R& I & fee	Dy No. 14608 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792399 dated 06-03-2019.
	Pharmacological Group	Other antidepressants ATC Code N06AX23
	Type of Form	Form 5
	Finished Product Specification	Not provided
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Extended release tablet (DIN 02535106) is Health Canada approved.
	Me-too status	Desven XR 50mg Tablet (For extended release tablet) Pharmevo (Pvt) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	 Latest GMP inspection report conducted within a period of last three years is required.
		 Finished product specifications are not provided. Applied product is film coated tablet. Formulation approved in reference regulatory authority (Health Canada) and in Pakistan is extended release tablet. Change in formulation from film coated to extended release tablet along with relevant fee is required.
	Decision: Deferred for following	
	Latest GMP inspection report conducted within last three years.	
	 Provision of finished pro 	<u>•</u>
		from film coated to extended release tablet as available in
	_	chority, along with prescribed fee as per notification No.F.7-
	11/2012- B&A/DRAP da	
653.	Name and address of	
055.	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)

	Brand Name +Dosage Form +	ZYTRIN 2mg tablet
	Strength	
	Composition	Each tablet contains: Terazosin (as Hydrochloride.2H ₂ 0) 2mg
	Diary No. Date of R& I & fee	Dy No. 14582 dated 07-03-2019 Fee paid PKR 20,000 vide Deposit Slip No. 0789185 dated 07-03-2019.
	Pharmacological Group	Alpha-adrenoreceptor antagonists ATC Code G04CA03
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Terazosin 2 mg Tablets
	Reference Regulatory	MHRA Approved
	Authorities.	PL 43870/0001
	Me-too status	Euzet 2mg Tablet
		Trigon Pharmaceuticals (Private) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period
		of last three years is required.
	Decision: Deferred for submission years.	on of latest GMP inspection report conducted within last three
654.	Name and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Tablet section (General)
	Brand Name +Dosage Form +	ZYTRIN 5mg tablet
	Strength	
	Composition	Each tablet contains:
		Terazosin (as Hydrochloride.2H ₂ 0) 5mg
	Diary No. Date of R& I & fee	Dy No. 14583 dated 07-03-2019 Fee paid PKR 20,000 vide Deposit Slip No. 0789186 dated 07-03-2019.
	Pharmacological Group	Alpha-adrenoreceptor antagonists ATC Code G04CA03
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Terazosin 5 mg Tablets
	Reference Regulatory	MHRA Approved
	Authorities.	PL 43870/0002
	Me-too status	Euzet 5mg Tablet
		Trigon Pharmaceuticals (Private) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period
		of last three years is required.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
655.		M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
055.	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Tablet section (General)
	Brand Name +Dosage Form + Strength	MEF tablets 500mg
	Composition	Each film coated tablet contains:
	D' N D C CDC 1 C C	Mefenamic acid500mg
	Diary No. Date of R& I & fee	Dy No. 14574 dated 07-03-2019 Fee paid PKR 20,000/- vide
	<u> </u>	D '. CI' NI 0000100 1 : 100 00 0010
	, n	Deposit Slip No. 0789177 dated 07-03-2019.
	Pharmacological Group	Deposit Slip No. 0789177 dated 07-03-2019. Anti-inflammatory and anti-rheumatic products, non-steroids ATC Code M01AG01

	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Mefenamic acid 500 mg film-coated tablets
	Reference Regulatory	MHRA Approved
	Authorities.	PL 13606/0258
	Me-too status	Megamef 500mg Tablet
		Mega Pharmaceuticals Limited
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period
		of last three years.
	Decision: Deferred for submission	on of latest GMP inspection report conducted within last three
	years.	
656.	Name and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Tablet section (General)
	Brand Name +Dosage Form +	RIFAREX tablet 550mg
	Strength	
	Composition	Each film tablet contains:
		Rifaxamin550mg
	Diary No. Date of R& I & fee	Dy No. 14579 dated 07-03-2019 Fee paid PKR 20,000/- vide
		Deposit Slip No. 0789182 dated 07-03-2019.
	Pharmacological Group	Antibiotics
		ATC Code A07AA11
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Xifaxan 550 mg film coated tablets
	Reference Regulatory	USFDA Approved
	Authorities.	
	Me-too status	Nyxia 550mg film coated tablet
		Pharmedic Laboratories (Pvt.) Ltd Lahore
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	• Latest GMP inspection report conducted within a period
		of last three years.
		on of latest GMP inspection report conducted within last three
(FF	years.	M/ I' DI C' I DI NI 2 CON CON I
657.	Name and address of	
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
	David Name (David Frame)	Tablet section (General)
	Brand Name +Dosage Form +	D-FEN SR tablet 100mg
	Strength	Fook delegand release tablet contains:
	Composition	Each delayed release tablet contains:
	Diam No Data of D & I & for	Diclofenac Sodium100mg
	Diary No. Date of R& I & fee	Dy No. 14568 dated 07-03-2019 Fee paid PKR 20,000/- vide
	Pharmacological Group	Deposit Slip No. 0789171 dated 07-03-2019.
	Pharmacological Group	Anti-inflammatory and anti-rheumatic products, non-steroids ATC Code M01AB05
	Type of Form	Form 5
	Type of Form Finished Product Specification	USP
	Pack size & Demanded Price	
		As per SRO Not available as 100mg deleved release arel tablet
	Approval status of product in Reference Regulatory	Not available as 100mg delayed release oral tablet
	Reference Regulatory Authorities.	
	Me-too status	Not available as 100mg deleved release and tablet
	WIC-100 Status	Not available as 100mg delayed release oral tablet
	CMP status	Last CMD inspection conducted on 10.07.2010
1	GMP status	Last GMP inspection conducted on 10-07-2019

	or change in formulation prescribed fee as per not Latest GMP inspection reserving Evidence of applied form	
(50		
658.	- 100	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Capsule section (General)
	Brand Name +Dosage Form +	OSPRA-PLUS Capsules 20/1100mg
	Strength	
	Composition	Each capsule contains:
		Omeprazole20mg
		Sodium bicarbonate1100mg
	Diary No. Date of R& I & fee	Dy No. 14576 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789179 dated 07-03-2019.
	Pharmacological Group	Proton pump inhibitors ATC Code A02BC01
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Zegerid capsule
	Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Outset Capsules
		GT Pharma (Pvt) Ltd., Lahore
		Reg. No. 86378
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period
		of last three years.
	Decision: Deferred for submission	on of latest GMP inspection report conducted within last three
	years.	
659.	Name and address of	,
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	LEFNO tablet 20mg
	Composition	Each film coated tablet contains: Lefnu20mg
	Diary No. Date of R& I & fee	Dy No. 14609 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792400 dated 06-03-2019.
	Pharmacological Group	Selective immunosuppressants ATC Code L04AA13
	Type of Form	Form 5
	Finished Product Specification	Not provided

Pack size & Demanded Price	As per SRO
Approval status of product in	Arava 20mg
Reference Regulatory	USFDA Approved
Authorities.	
Me-too status	Leforex 20mg tablet
	DeMont Research Laboratories (Pvt) Ltd., Sheikhupura
GMP status	Last GMP inspection conducted on 10-07-2019
Remarks of the Evaluator ^{xxiii} .	 Latest GMP inspection report conducted within a period of last three years is required. Product is available in BP. Finished product specifications are required. Change in label claim to read: "Each film coated tablet contains: Leflunomide20mg", along with requisite fee.

Decision: Deferred for following:

- Change in label claim to read
 - "Each film coated tablet contains:
- Leflunomide......20mg", along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.
- Change in product specifications to BP Specifications.
- Latest GMP inspection report conducted within last three years.

	Latest Givii inspection i	cport conducted within last time years.
660.	Name and address of manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Tablet section (General)
	Brand Name +Dosage Form +	LAXMAC tablet 60mg
	Strength	
	Composition	Each film coated tablet contains:
		Loxoprefen Sodium as Hydrate60mg
	Diary No. Date of R& I & fee	Dy No. 14571 dated 07-03-2019 Fee paid PKR 20,000/- vide
		Deposit Slip No. 0789174 dated 07-03-2019.
	Pharmacological Group	Analgesic, anti-inflammatory, anti-pyretic
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not available for film coated tablet and applied composition
	Me-too status	Loxonin 60mg film coated tablet
		Evolution Pharmaceuticals (Pvt.) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	 Latest GMP inspection report conducted within a period of last three years is required.
		 Composition approved in PMDA Japan is Loxoprofen sodium hydrate (JP) 68.1mg (Brand name Kunihiro) whereas applied composition is Loxoprefen Sodium as Hydrate 60mg. Change in composition according to RRA is required along with relevant fee. Applied product is film coated tablet. Evidence of product approved in PMDA, Japan is of uncoated tablets. Approval of film coated tablet in reference regulatory authority or change of formulation from film coated to
		product approved in PMDA, Japan is of unco Approval of film coated tablet in reference

Decision: Deferred for following:

• Change in formulation from film coated to uncoated tablet as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

	sodium hydrate (JP) 68.1 prescribed fee as per no fee of registration). • Latest GMP inspection re	from Loxoprefen Sodium as Hydrate 60mg to Loxoprofen Img as available in reference regulatory authority, along with tification No.F.7-11/2012- B&A/DRAP dated 13-07-2021 (full eport conducted within last three years.
661.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	Dexamax Cream 5% w/w
	Composition	Each gram cream contains: Dexamethasone Sodium Phosphate 5% w/w
	Diary No. Date of R& I & fee	Dy No. 16727 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 072369 dated 07-03-2019
	Pharmacological Group	Corticosteroids, moderately potent (group II) ATC Code D07AB19
	Type of Form Finished Product Specification	Form 5 USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	 Latest GMP inspection report conducted within a period of last three years. Evidence of separate dispensing facility for dispensing of steroidal materials is required.
		 Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required.
		 Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision: Deferred for following: • Latest GMP inspection report conducted within last three years clearly mentioning	
	 availability of separate dispensing facility or otherwise, for dispensing of steroidal raw materials. Evidence of approval of applied formulation in reference regulatory 	
	1	ch were adopted by Registration Board in its 275th meeting)
	or change in formulation as available in reference regulatory authority, along with	
prescribed fee as per notification No.F.7-11/2012- B&A/DRAP da • Evidence of applied formulation/drug already approved by DR status) along with registration number, brand name and name of		nulation/drug already approved by DRAP (generic / me-too
662.	Name and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form + Strength	Skinton 20% Cream
	Composition	Each gram of cream contains: Azelaic acid0.2gm/gm
	Diary No. Date of R& I & fee	Dy No. 16724 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0804196 dated 07-03-2019
	Pharmacological Group	Other anti-acne preparations for topical use ATC Code D10AX03

TO CT	Б	
Type of Form	Form 5	
Finished Product Specification	Innovator's Specifications	
Pack size & Demanded Price	As per SRO	
Approval status of product in	Azelex 20% topical cream	
Reference Regulatory	USFDA Approved	
Authorities.		
Me-too status	Ezalic 20% cream	
	Evolution Pharmaceuticals (Pvt.) Ltd	
GMP status	Last GMP inspection conducted on 10-07-2019	
Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period of last three years.	
	of last three years.	
	 Change of label claim according to composition given in 	
	USFDA, as follows:	
	"Each gram of cream contains Azelaic acid0.2 gm	
	(20% w/w)" along with requisite fee.	
Decision: Deferred for following:		

- Change of label claim according to composition given in USFDA, as follows:
- "Each gram of cream contains Azelaic acid........0.2 gm (20% w/w)" along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.

Latest GMP inspection report conducted within last three years.

	Latest GMF Hispection r	eport conducted within last tiffee years.
663.	Name and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form +	PERLIC 1% cream
	Strength	
	Composition	Each gram of cream contains:
		Lindane0.01gm/gm
	Diary No. Date of R& I & fee	Dy No. 14591 dated 07-03-2019 Fee paid PKR 20,000/-vide
		Deposit Slip No. 0789195 dated 07-03-2019
	Pharmacological Group	Ectoparasiticides, including Scabicides
		ATC Code P03AB02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Not found
	Reference Regulatory	
	Authorities.	
	Me-too status	Line Cream
		Shaigan Pharmaceuticals (Pvt) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period
		of last three years.
		Evidence of approval of applied formulation in reference
		regulatory authorities/agencies which were
		declared/approved by the Registration Board in its 275th
		meeting is required.
		Change of label claim according to label claim of me-too
		product, as follows:
		"Each gram of cream contains Lindane10mg"
		along with requisite fee.

Decision: Deferred for following:

- Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting,
- Latest GMP inspection report conducted within last three years.
- Change of label claim according to label claim of me-too product, as follows: "Each gram of cream contains Lindane.......10mg" along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.

664.	Name and address of		
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)	
	Brand Name +Dosage Form + Strength	NCIN Ointment 5% w/w	
	Composition	Each gram contains:	
	Diary No. Date of R& I & fee	Neomycin sulphate5% w/w Dy No. 14601 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792391 dated 06-03-2019	
	Pharmacological Group	Other antibiotics for topical use ATC Code D06AX04	
	Type of Form	Form 5	
	Finished Product Specification	USP	
	Pack size & Demanded Price	As per SRO	
	Approval status of product in Reference Regulatory Authorities.	Not found	
	Me-too status	Not found in applied strength	
	GMP status	Last GMP inspection conducted on 10-07-2019	
	Remarks of the Evaluator ^{xxiii} .	 Latest GMP inspection report conducted within a period of last three years. 	
		Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required.	
		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is	
		required.	
	Decision: Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275 th meeting,		
	• Evidence of applied for status) along with registr	mulation/drug already approved by DRAP (generic / me-too ration number, brand name and name of firm.	
		eport conducted within last three years.	
665.	Name and address of manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)	
	Brand Name +Dosage Form + Strength	Cream/Ointment/Gel section (General) LURBI GEL	
	Composition	Each gram of gel contains: Flurbiprofen0.05gm/g	
	Diary No. Date of R& I & fee	Dy No. 14529 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792389 dated 06-03-2019	
	Pharmacological Group	Anti-inflammatory preparations, non-steroids for topical use ATC Code M02AA19	
	Type of Form	Form 5	
	Finished Product Specification	BP, as stated by applicant	
	Pack size & Demanded Price	As per SRO	
	Approval status of product in Reference Regulatory	Not found	
	Authorities.	Relaxoen Gel	
	Me-too status	E-Pharm Laboratories, A-40 S.I.T.E Super Highway North Karachi, Karachi	
	GMP status	Last GMP inspection conducted on 10-07-2019	
	OIVII status	Last OWIT Inspection conducted on 10-07-2017	

Remarks of the Evaluator ^{xxiii} .	 Latest GMP inspection report conducted within a period of last three years. Finished product monograph is not available in BP, USP or JP. Provision of BP monograph of applied product or change in specifications of finished product along with prescribed fee is required. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required. Change label claim to read as follows: "Each gram of gel contains: Electric for a contains:
	Flurbiprofen0.05gram", along with submission of requisite fee.

Decision: Deferred for following:

- Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
- Latest GMP inspection report conducted within last three years.
- Change label claim to read as follows:
 - "Each gram of gel contains: Flurbiprofen......0.05gram", along with submission of prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.
- Provision of BP monograph of applied product or, in case of unavailability, change in specifications of finished product from BP to Manufacturer's Specifications along with prescribed fee.

	prescribed fee.		
666. N	ame and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National	
m	nanufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)	
		Cream/Ointment/Gel section (General)	
В	rand Name +Dosage Form +	Molyfax Plus Ointment	
St	trength		
C	omposition	Each gram ointment contains:	
	-	Polymyxin B Sulfate10,000 units	
		Bacitracin Zinc500 units	
		Lignocaine4%	
D	iary No. Date of R& I & fee	Dy No. 14600 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792390 dated 06-03-2019	
P	harmacological Group	Other antibiotics for topical use	
		ATC Code D06AX05	
T	ype of Form	Form 5	
Fi	inished Product Specification	USP Specifications	
P	ack size & Demanded Price	As per SRO	
R	pproval status of product in eference Regulatory uthorities.	Not confirmed	
	le-too status	Not available in combination with lignocaine	
G	MP status	Last GMP inspection conducted on 10-07-2019	
R	emarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period of last three years.	
		 Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required. Evidence of applied formulation/drug already approved 	
		by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.	
$\overline{\mathbf{D}}$	ecision: Deferred for following:	•	

	 agencies which were ado Evidence of applied form status) along with registr Latest GMP inspection r 	f applied formulation in reference regulatory authorities / pted by the Registration Board in its 275 th meeting, mulation/drug already approved by DRAP (generic / me-too ation number, brand name and name of firm. eport conducted within last three years.	
667.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)	
	Brand Name +Dosage Form + Strength	BETA-BC CREAM	
	Composition	Each gram of cream contains: Betamethasone(as dipropionate)USP0.5mg (0.05% w/w) Clotrimazole USP10mg (1% w/w)	
	Diary No. Date of R& I & fee	Dy No.14729 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792382 dated 06-03-2019	
	Pharmacological Group	Antifungals for topical use ATC Code D01A	
	Type of Form	Form 5	
	Finished Product Specification	USP	
	Pack size & Demanded Price Approval status of product in	As per SRO Lotrisone topical cream	
	Reference Regulatory Authorities.	USFDA Approved	
	Me-too status	Betazole Cream Xenon Pharamaceuticals (Pvt) Ltd., Lahore	
	GMP status	Last GMP inspection conducted on 10-07-2019	
	Remarks of the Evaluator ^{xxiii} .	 Latest GMP inspection report conducted within a period of last three years. Evidence of separate dispensing facility for dispensing of steroidal materials is required 	
		IP inspection report conducted within last three years clearly ate dispensing facility or otherwise, for dispensing of steroidal	
668.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)	
	Brand Name +Dosage Form + Strength	BETA-D CREAM	
	Composition	Not given	
	Diary No. Date of R& I & fee	Dy No.16730 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792383 dated 06-03-2019	
	Pharmacological Group	Corticosteroids, potent (group III) ATC Code D07AC01	
	Type of Form	Form 5 not provided	
	Finished Product Specification	Not stated	
	Pack size & Demanded Price Approval status of product in	Not stated Not stated	
	Reference Regulatory Authorities.	Not stated	
	Me-too status	Not stated	
	GMP status	Last GMP inspection conducted on 10-07-2019	
	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period of last three years.	
		 Complete application on Form 5 and all required undertakings duly signed and stamped by company's authorized representative are required. 	

		Evidence of separate dispensing facility for dispensing of	
		steroidal materials is required.	
	Č	ected the application is not submitted on Form 5.	
669.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000810) Cream/Ointment/Gel section (General)	
	Brand Name +Dosage Form + Strength	BREN GEL 10%	
	Composition	Each gram of gel contains: Ibuprofen 100mg/g	
	Diary No. Date of R& I & fee	Dy No. 14595 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792385 dated 06-03-2019	
	Pharmacological Group	Anti-inflammatory preparations, non-steroids for topical use ATC Code M02AA13	
	Type of Form	Form 5	
	Finished Product Specification	BP Specifications	
	Pack size & Demanded Price	As per SRO	
	Approval status of product in	Fenbid Forte 10% Gel	
	Reference Regulatory	PL 10972/0082	
	Authorities.	MHRA Approved.	
		However, the approved product contains 1mg of Benzyl alcohol	
		per 100mg as excipient with known effect.	
	Me-too status	Fynkoben Cream	
		FYNK Pharmaceuticals, Lahore.	
	GMP status	Last GMP inspection conducted on 10-07-2019	
	Remarks of the Evaluator ^{xxiii} .	• Latest GMP inspection report conducted within a period of last three years.	
		 Revision of master formulation according to composition given in MHRA along with relevant fee. 	
	 Decision: Deferred for following: Latest GMP inspection report conducted within last three years. Revision of master formulation according to composition given in MHRA along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021. 		
670.	Name and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National	
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)	
		Cream/Ointment/Gel section (General)	
	Brand Name +Dosage Form + Strength	LIGAIN 5% OINTMENT	
	Composition	Each gram of cream contains:	
		Lidocaine(Lignocaine)0.05gm/gm	
	Diary No. Date of R& I & fee	Dy No. 14572 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0789175 dated 07-03-2019	
	Pharmacological Group	Local anaesthetic	
	Type of Form	Form 5	
	Finished Product Specification	USP Specifications	
	Pack size & Demanded Price	As per SRO	
	Approval status of product in Reference Regulatory Authorities.	Not confirmed	
	Me-too status	Xyloaid 5% Ointment Reg. No. 23075	
	GMP status	Last GMP inspection conducted on 10-07-2019	
	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period of last three years.	
		Change label claim to read as follows:	
	1		

		"Each gram of ointment contains:
		Lidocaine(Lignocaine)0.05gm", along with
		submission of requisite fee.
		• Evidence of approval of applied formulation in reference
		regulatory authorities/agencies which were
		declared/approved by the Registration Board in its 275th
		meeting is required.
	Decision: Deferred for following	
	 Evidence of approval o 	f applied formulation in reference regulatory authorities /
	agencies which were ado	pted by the Registration Board in its 275th meeting,
	 Change label claim to rea 	ad as follows:
		t contains: Lidocaine(Lignocaine)0.05gm", along with
		ification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.
	 Latest GMP inspection r 	eport conducted within last three years.
671.	Name and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Cream/Ointment/Gel section (General)
	Brand Name +Dosage Form +	FUDE-B CREAM
	Strength	
	Composition	Each gram cream contains:
		Fusidic acid20mg (2%)
		Betamethasone (as valerate)1mg
	Diary No. Date of R& I & fee	Dy No. 14596 dated 07-03-2019 Fee paid PKR 20,000/-vide
	_ = === , = = = = = = = = = = = = = = =	Deposit Slip No. 0792386 dated 06-03-2019
	Pharmacological Group	Corticosteroids, potent, combinations with antibiotics
	Thursday or ogress or out	ATC Code D07CC01
	Type of Form	Form 5
	Finished Product Specification	USP Specifications, as stated by the applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Xemacort 20 mg/g + 1 mg/g cream
	Reference Regulatory	PL 04569/1625
	Authorities.	MHRA Approved
	Me-too status	Baxidin-B Cream
		Reg. No. 67597
		Baxter Pharmaceuticals, A-1/A Scheme No. 33 Phase-I S.I.T.E.
		Super Highway Karachi., Karachi
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period
		of last three years.
		• Form 5 and all required undertakings duly signed and
		stamped by company's authorized representative are
		required.
		• Finished product is not available in USP. Change of
		specifications from USP to Manufacturer's
		specifications along with relevant fee is required.
	Decision: Registration Board rei	ected the application since the application is not signed by
	9	annot be considered for evaluation.
672.	Name and address of	
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Tablet section (General)
	Brand Name +Dosage Form +	T-PAR tablet 75/650mg
	Strength	True more verse one
	Composition	Each film coated tablet contains:
		Tramadol75mg
		Acetaminophen650mg
	Diary No. Date of R& I & fee	Dy No. 14590 dated 07-03-2019 Fee paid PKR 20,000/-vide
		Deposit Slip No. 0789194 dated 07-03-2019
	1	= 1p 1111 Sup 1101 0101 121 1 dated 01 00 2017

	Pharmacological Group	Opioids in combination with non-opioid analgesics ATC Code N02AJ13
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not available in film coating
	Me-too status	Tonoflex-P Forte Tablets 75mg/650mg
		Reg. No. 94798
		SAMI Pharmaceuticals Pvt. Ltd.
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	• Latest GMP inspection report conducted within a period of last three years.
		Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required.
		 Applied formulation includes Tramadol 75mg, whereas formulation of product registered in DRAP and in USP includes Tramadol Hydrochloride 75mg. Change of acid/base form to salt form along with relevant fee is required.
	 Evidence of approval o agencies which were ado Change of acid/base form 	eport conducted within last three years. If applied formulation in reference regulatory authorities / pted by the Registration Board in its 275 ^a meeting. In of API to salt form as already registered by DRAP along with ification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.
673.	Name and address of	
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)
		Tablet section (General)
	Brand Name +Dosage Form + Strength	FLAVO tablet 500mg
	Composition	Each film coated tablet contains:
	Diary No. Date of R& I & fee	Micronized purified flavonoid fraction Dy No. 14593 dated 07-03-2019 Fee paid PKR 20,000/-vide
	Diary No. Date of R& 1 & Ice	Deposit Slip No. 0789197 dated 07-03-2019 Deposit Slip No. 0789197 dated 07-03-2019
	Pharmacological Group	Vasoprotective
	Type of Form	Form 5
	Finished Product Specification	USP Specifications, as stated by the applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed as complete composition is not provided
	Me-too status	Not found as complete composition is not provided
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator ^{xxiii} .	• Latest GMP inspection report conducted within a period of last three years.
		 Master formulation describing quantities of actives and excipients along with the justification/role each ingredient.
		Label claim does not include quantity of API. Label claim needs to be revised according to the master formulation.

- Finished product is not available in USP. Change of specifications from USP to Manufacturer's specifications along with relevant fee is required.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting is required.
- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.

Decision: Deferred for following:

- Latest GMP inspection report conducted within last three years.
- Submission of master formulation describing quantities of actives and excipients along with the justification/role each ingredient.
- Revision of label claim as per master formulation to include quantity of API.
- Justification of submitted finished product specifications, since firm has claimed USP specifications whereas USP monograph is not available for applied formulation. In case of change from USP to Manufacturer's specifications, firm shall submit prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.
- Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

	status) along with registr	ration number, brand name and name of firm.	
674.	Name and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National	
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)	
		Tablet section (General)	
	Brand Name +Dosage Form +	NARTIDAC tablet 1.5/5mg	
	Strength	· ·	
	Composition	Each film coated modified release tablet contains:	
		Indapamide1.5mg	
		Amlodipine (as besilate)5mg	
	Diary No. Date of R& I & fee	Dy No. 16725 dated 07-03-2019 Fee paid PKR 20,000/-vide	
		Deposit Slip No. 0792381 dated 06-03-2019	
	Pharmacological Group	Calcium channel blockers and diuretics	
		ATC Code C08GA02	
	Type of Form	Form 5	
	Finished Product Specification	USP Specifications, as stated by the applicant	
	Pack size & Demanded Price	As per SRO	
	Approval status of product in	Not confirmed	
	Reference Regulatory		
	Authorities.		
	Me-too status	Natrilam 5 mg Tablets	
		Reg. No. 90507	
		Servier Research and Pharmaceuticals Pakistan (Pvt) Ltd.,	
		Lahore	
	GMP status	Last GMP inspection conducted on 10-07-2019	
	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period	
		of last three years.	
		• Finished product is not available in USP or any other	
		pharmacopoeia. Change of specifications from USP to	
		Manufacturer's specifications along with relevant fee is	
		required.	
		Evidence of approval of applied formulation in reference	
		regulatory authorities/agencies which were	
		declared/approved by the Registration Board in its 275th	
		meeting is required.	

Decision: Deferred for following:

- Latest GMP inspection report conducted within last three years.
- Justification of submitted finished product specifications, since firm has claimed USP specifications whereas USP monograph is not available for applied formulation. In case of change from USP to Manufacturer's specifications, firm shall submit prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.
- Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.

	agencies which were adopted by the Registration Board in its 275 th meeting.		
675.	Name and address of	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National	
	manufacturer / Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810)	
		Tablet section (General)	
	Brand Name +Dosage Form +	LORA-P CR 5mg/120mg tablet	
	Strength		
	Composition	Each film coated controlled release tablet contains:	
		Loratidine USP5mg	
		Pseudoephedrine Sulphate USP120mg	
	Diary No. Date of R& I & fee	Dy No. 14573 dated 07-03-2019 Fee paid PKR 20,000/-vide	
		Deposit Slip No. 0789176 dated 07-03-2019	
	Pharmacological Group	Nasal decongestants for systemic use	
		ATC Code R01BA52	
	Type of Form	Form 5	
	Finished Product Specification	Manufacturer's Specifications	
	Pack size & Demanded Price	As per SRO	
	Approval status of product in	Claritin-D 12 hour extended release tablet	
	Reference Regulatory	Bayer Healthcare LLC	
	Authorities.	USFDA Approved	
	Me-too status	Not found	
	GMP status	Last GMP inspection conducted on 10-07-2019	
	Remarks of the Evaluator ^{xxiii} .	Latest GMP inspection report conducted within a period	
		of last three years.	
		Change of master formulation to include Loratidine is	
		required along with requisite fee.	
		Evidence of applied formulation/drug already approved	
		by DRAP (generic / me-too status) along with	
		registration number, brand name and name of firm is	
		required.	

Decision: Deferred for following:

- Latest GMP inspection report conducted within last three years.
- Change of master formulation to include Loratidine along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.
- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

Agenda of Mr. Ishtiaq

Case: Registration applications of local manufacturing of human drugs submitted on CTD format (New Section)

On the recommendations of panel of experts, the CLB in its 276th meeting held on 03rd September, 2020 has considered and approved the grant of Drug Manufacturing License in the name of M/s Alpenglow pharmaceuticals (Pvt) Ltd, Plot No. A7, Risalpur Export Processing Zone, Risalpur.

- i. Capsule (Cephalosporin)
- ii. Dry Powder injection section (Cephalosporin) (1 molecule / 7 products)
- iii. Dry powder suspension section (Cephalosporin) (1 molecule / 2 products)
- iv. Tablet (Psychotropic)

6.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan
	Status of the applicant	 ✓ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☑ Domestic sale☐ Export sale☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. Dated 24/02/2022
	Details of fee submitted	PKR 30,000/-: Dated 20/10/2021
	The proposed proprietary name / brand name	CIAXON 2 gm IV Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone as Sodium2 gm
	Pharmaceutical form of applied drug	Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, Third-generation cephalosporins.
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rocephin 2 gm IV Injection (USFDA Approved).
	For generic drugs (me-too status)	Oxidil 2 gm IV injection
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ceftriaxone Sodium is present in USP. The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		(impurity A & unspec analytical procedures analysis and justificati	and its verification, batch ion of specification, reference osure system and stability	
Stability studies		months Accelerated: 40°C ± 2 months	ions: C / 65% ± 5%RH for 72 C°C / 75% ± 5%RH for 6 011302002, 011302003)	
Module-III (Drug Product):		including its description pharmaceutical development manufacturing process validation protocols, of drug product, specific validation of analytical justification of specific	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Pharmaceutical equivalence has been established against the brand leader that is Aventrix 250mg Injection by Sanofi Aventis Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).	
Pharmaceutical equidissolution profile	Pharmaceutical equivalence and comparative dissolution profile			
Analytical method validation/verification of product		Method verification studies have submitted including linearity, range, accuracy, precision, specificty.		
STABILITY STUDY DA	TA			
Manufacturer of API	M/S Sinopharm Weig	ida Pharmaceutical Co., I	_td.	
API Lot No.	Q0121039028			
Description of Pack (Container closure system	Powder ceftriaxone in	Sealed with printed A.for a clear glass vial One Amp mbossed board unit cartor	poule of water for injection and	
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			
Frequency Accelerated: 0, Real Time: 0, 3				
Batch No.	013	014	015	
Batch Size	750 Vials	750 Vials	750 Vials	
Manufacturing Date	06-2021	06-2021	06-2021	
Date of Initiation	09-06-2021	09-06-2021	09-06-2021	
No. of Batches	03			
DOCUMENTS /DATA P	ROVIDED BY THE APPI	LICANT		
	ous approval of application data of the firm (if any)	The firm has not subm	nitted any document.	

Copy of GMP certificate No. SX20180229 issued by CFDA valid till 05/06/2023.
Copy of letter No.0090/2021/DRAP-CPS/1330 CD(I&E) dated 16/04/2021 is submitted wherein the permission to import different APIs ceftriaxone as sodium for the purpose of test/analysis and stability studies is granted. AHPAO505150 dated 04/05/2021
Submitted
Submitted
Submitted

Remarks of Evaluator

Sr.#	Section	Observation
	3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.
	3.2.S.4.3	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.
	3.2.S.4.4	The tests for crystallinity and particulate matter are not performed by drug product manufacturer. The assay limit specified by drug substance manufacturer (>84.0%) is different from that specified by drug product manufacturer (NLT 79%). Justification is required.
	3.2.S.5	Provide COA of reference standard which is actually used in the analysis of drug substance.
	3.2.P.1	Submit master formulation including theoretical fill weight per vial.
	3.2.P.2.2.1	Pharmaceutical equivalence of the applied drug shall be established with the innovator/reference product and results of all the quality tests of the developed formulation and the innovator / reference product shall be submitted. Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.
	3.2.P.3.5	Justify your process validation protocols without any process for optimization of sterilization process and sealing of vials etc.
	3.2.P.5.1	Specifications of the drug product does not include tests as recommended by USP including test for constituted solution, crystallinity and complete assay test.
	3.2.P.5.2	Provide detailed testing method for the applied drug product instead of submitting copy of USP monograph.
	3.2.P.5.3	Provide standard and sample preparation method used in analytical method verification studies. Specify the details of the accuracy and specificity test including the details of concertation of 80%, 100% and 120% solutions. Test method for Empazin 25mg Tablet is provided in analytical method verification studies.

3.2.P.5.3	Justification of method of specificity test in analytical method verification studies shall be submitted. Clarification is required. Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. The peak area of standard solution concentration in analytical method verification studies is approximately 6472293 while the peak area of the standard solution of same concentration in stability studies is 436282 approximately. Clarify the difference in peak areas.
3.2.P.6	Provide COA of reference standard actually used in the analysis of drug product.
3.2.P.8	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. Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch. The tests for water contents, constituted solution etc are not performed during stability studies since these tests are required to make assessment of the stability profile. Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing. Reference of previous approval of applications with stability study data of the firm (if any).

Decision of 322nd Meeting of Registration board: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Sr.#	Section	Observation	Response of firm
1.	3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.	Firm has submitted copies of the Drug substance specifications and analytical procedures
2.	3.2.S.4.3	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	Firm has submitted analytical method verification studies including specificity, accuracy and repeatability
3.	3.2.S.4.4	The tests for crystallinity and particulate matter are not performed by drug product manufacturer.	The crystalanity test was not performed. However particulate matter test is not mentioned by USP for the raw material, instead it is for product.
		The assay limit specified by drug substance manufacturer (>84.0%) is different from that specified by drug product manufacturer (NLT 79%). Justification is required.	The drug substance manufacturer follows USP as well as Chinese Pharmacopoeia monograph for ceftriaxone sodium, So claims the assay limit of > 84 %. While being the drug product manufacturer we have followed the USP Monograph for ceftriaxone and USP specifies the limit NLT 79.5%. Moreover, the raw material manufacturer limits are strict in this regard so material that comply the manufacturer specifications will definitely meets the USP Specification.

4.	3.2.S.5	Provide COA of reference standard which is actually used in the analysis of drug substance.	Firm has submitted COA of reference standard.		
5.	3.2.P.1	Submit master formulation including theoretical fill weight per vial.	Firm has Submitted master formulation		
6.	S.2.P.2.2.1 Pharmaceutical equivalence of the applied drug shall be established with the innovator/reference product and results of all the quality tests of the developed formulation and the innovator / reference product shall be submitted. Compatibility studies for the dry powder for has n		• Firm has provided Pharmaceutical equivalence studies against Rocephin Injection by performing following parameters appearance, identification, pH, clarity of solution and assay. However, firm has not provided batch details of innovator product.		
7.	3.2.P.3.5	Justify your process validation protocols without any process for optimization of sterilization process and sealing of vials etc.	Firm has submitted revised process validation protocols		
8.	3.2.P.5.1	Specifications of the drug product does not include tests as recommended by USP including test for constituted solution, crystallinity and complete assay test.	No justification provided		
9.	3.2.P.5.2	Provide detailed testing method for the applied drug product instead of submitting copy of USP monograph.	Firm has submitted new method for testing of finished drug product.		
10.	3.2.P.5.3	Provide standard and sample preparation method used in analytical method verification studies. Specify the details of the accuracy and specificity test including the details of concertation of 80%, 100% and 120% solutions. Test method for Empazin 25mg Tablet is provided in analytical method verification studies.	preparation method used in analytical method verification studies. Firm has submitted method verification studies.		
11.	3.2.P.5.3	 Justification of method of specificity test in analytical method verification studies shall be submitted. Clarification is required. Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. The peak area of standard solution concentration in analytical method verification studies is approximately 6472293 while the peak area of the standard solution of same concentration in stability studies is 436282 approximately. Clarify the difference in peak areas. 	The reason for area difference is that in verification studies the injection volume was different, that is		
12.	3.2.P.6	Provide COA of reference standard actually used in the analysis of drug product.	Firm has provided COA of reference standard.		
13.	3.2.P.8	• In-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.	Firm has submitted In-use studies for drug products for 24 hours Complete stability data not submitted.		
		Provide raw data sheets to justify the calculation of results for assay testing at each	The constituted solution was		

time point during the stability testing of each checked at every point of stability studies since the assay is performed batch. after reconstituting the injection. So • The tests for water contents, constituted after reconstitution and before assay solution etc are not performed during stability the injection was checked for studies since these tests are required to make assessment of the stability profile. particulate matter in injection or any foreign particle. At all points the results were satisfactory according to USP specified limits. However, justification not provided for water content test. Not submitted • Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Reference previous of approval applications with stability study data of the firm (if any).

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.

677.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan		
	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7, Export Processing Zone Risalpur, District Nowshera (KP) Pakistan		
	Status of the applicant	 ☑ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver) 		
	Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	☑ Domestic sale☐ Export sale☐ Domestic and Export sales		
	Dy. No. and date of submission	Dy. No. 5860 Dated 03-03-2022		
	Details of fee submitted	PKR 30,000/-: Dated 25-01-2022		
	The proposed proprietary name / brand name	PENSEF 500mg Capsule		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cephradine as monohydrate500mg		
	Pharmaceutical form of applied drug	Hard Gelatin capsule		
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, First-generation cephalosporins.		

Reference to Finished product specifications	USP		
Proposed Pack size	1x12's As per SRO		
Proposed unit price			
The status in reference regulatory authorities	Cefradine 500mg Capsules (MHRA Approved).		
For generic drugs (me-too status)	Velosef 500 mg Capsule		
GMP status of the Finished product manufacturer	New license granted on 22-09-2020.		
Name and address of API manufacturer.	M/s Zhejiang Anglikang Pharmaceutical Co. Ltd No. 1000 Shengzhou North Road, Shengzhou, Shaoxing, China.		
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and control impurities, specifications, analytical procedures a its verification, batch analysis and justification of specification, reference standard, container closus system and stability studies of drug substance and drug product is submitted.		
Module III (Drug Substance)	Official monograph of Cephradine as Monohydra is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and control tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, referensiandard, container closure system and stability studies of drug substance		
Stability studies	Stability study conditions: Real time: $5^{\circ}C \pm 3^{\circ}C$ for 36 months Accelerated: $25^{\circ}C \pm 2^{\circ}C / 60\% \pm 5\%$ RH for 6 months Batches: (32051704109, 32051704110, 32051704111)		
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and control impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analytication of specification, reference stand container closure system and stability studies of product.		
Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Velosef 500 mg Capsule by Glaxosmithkline Pakistan Limited by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand is Velosef 500 mg Capsule by Glaxosmithkline		

			Pakistan Limited in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.			
	Analytical method validation/verification of product		Method verification studies have submitted including linearity, range, accuracy, precision, specificity.			
STAB	ILITY STUDY DA	TA				
Manu	facturer of API		M/s Zhejiang Anglikang Pharmaceutical Co. Ltd., No. 1000 Shengzhou North Road, Shengzhou, Shaoxing, China.			
API L	ot No.	00203-08/110/2021	00203-08/110/2021			
	ption of Pack niner closure system	Blister packof 2x6's, Pr	inted Unit Carto	on, Product In	sert	
Stabili	ty Storage Conditio	n Real time: $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / Accelerated: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$		Н		
Time 1	Period	Real time: 6 months Accelerated: 6 months				
Freque	ency	Accelerated: 0, 2, 4, 6 (Real Time: 0, 3, 6 (Mor				
Batch	No.	004	005		006	
Batch	Size	10000 Capsules	10000 Capsulo	es	10000 Capsules	
Manu	facturing Date	06-2021	06-2021		06-2021	
Date of	of Initiation	14-06-2021	14-06-2021		14-06-2021	
No. of	Batches	03				
Admii	nistrative Portion					
		ous approval of applications data of the firm (if any)	The firm has not submitted any document.			
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		The firm has submitted copy of GMP certificate of M/s Zhejiang Anglikang pharmaceutical Co. Ltd. China issued by China Food and Drug administration. It is valid till 30-08-2020.			
	Documents for the procurement of API with approval from DRAP (in case of import).		The firm has submitted copy of invoice (2021042801) specifying purchase of Cephradine compacted (100kg, Batch # 32052010034) attested by Assistant Director (I &E), Peshawar dated 18-05-2021.			
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		Submitted			
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Submitted				
	ks of Evaluator:			Γ		
Sr.#		Observation Conies of the Drug substance	Response of firm			
1.		Copies of the Drug substance specifications and analytical				
		used for routine testing of the			procedures used for routine testing	

	<u> </u>		
		substance/ Active pharmaceutical	of the Drug substance/ Active
		ingredient by both drug substance & drug	pharmaceutical ingredient by both
		product manufacturer is required.	drug substance & drug product
			manufacturer have been submitted
2.	3.2.S.4.3	Analytical method Verification studies	Analytical method Verification
		including specificity, accuracy and	studies including specificity,
		repeatability (method precision) performed	accuracy and repeatability (method
		by the Drug product manufacturer for both	precision) performed by the Drug
		compendial as well as non-compendial	product manufacturer have been
		drug substance(s) shall be submitted.	submitted
3.	3.2.S.4.4	The Submitted COA of Drug substance	Firm has stated that in the testing of
		and drug product manufacturer does not	Raw material the peak of
		include contents of cephalexin as	Cephalexin is also present in the
		recommended by USP (NMT 5.0%)	chromatogram, so the results of
			cephalexin can be calculated from
		The submitted COA from drug product	Chromatogram.
		manufacturer is not readable. Provide	COA of batch no. 32052010034 has
		readable copy of COA.	been submitted.
4	3.2.S.5	Provide COA of reference standards for	Firm has provided in house
		both cephradine and cephalexin which is	working standard COA of
		actually used in the analysis of drug	Cephradine compacted of batch no.
		substance including source and lot number.	32052010034
5.	3.2.S.7	The details of batches of stability study	Firm has submitted following
	6.2.2.7	data of drug substance in module 3 are	batches(32051704109,
		different from the bathes provided in	32051704112, 32051704111)
		module 2.	02001701112, 02001701111)
6.	3.2.P.1	Submit master formulation including	Submitted
0.	3.2.1 .1	theoretical fill weight per bottle along with	Saomice
		details of equivalency factor for	
		cephradine.	
		copinadine.	
		List all components of the dosage form,	
		and their amount on a per unit basis (
		including overages, if any), the function of	
		the components, and a reference to their	
		quality standards (e.g. compendial	
		monographs or manufacturer's	
		specifications).	
7.	3.2.P.2.2.1	Justify why drug release studies	Du to unavailability of innovator.
'	5.2.1 .2.2.1	/comparative Dissolution studies were not	
		performed Against innovators product.	
		Justify how same results are obtained for	
		Pharmaceutical equivalence and CDP	CDP of both strengths are different.
		studies for both Cephradine 250mg and	In dossier while compiling same
		500mg Capsule	CDP was attached for both
			strengths.
8.	3.2.P.2.2.4	Justify why the tests of reconstitution time	Both reconstitution test and test for
		, clarity and colour after reconstitution are	clarity of solution are for
		included in this section. Moreover, flow	ceftriaxone injection, while drafting
		chart of manufacturing also showed the	these test appeared in these section.
		process for dry powder for suspension.	Treates in these section.
9.	3.2.P.3	A batch formula for proposed commercial	submitted
.	3.2.1 .3	batch size shall be provided that includes a	suchinicu
		list of all components of the drug product	
		to be used in the manufacturing process,	
		their amounts on a per batch basis, and a	
		reference to their quality standards.	
	i	reference to their quality standards.	

11.	3.2.P.5.1 3.2.P.5.2	The test for uniformity of dosage unit, deliverable volume and water determination are not added in specifications as recommended in USP monograph. Revise your specifications as per USP monograph along with submission of applicable fee. The assay limits mentioned in specifications are 90%-102% which are different from USP specifications (90%-125%) Provide detailed method of analysis of the drug product in section 3.2.P.5.2 instead of providing copy of USP monograph.	Firm has submitted revised specifications. However requisite fee for change in specifications has not been submitted. Submitted
12.	3.2.P.5.3	Provide standard and sample preparation method used in analytical method verification studies. Justify method verification studies of drug without performance of specificity test. Specify the details of the accuracy and specificity test including the details of concentration of 80%, 1005 and 120% solutions. Test method for Empazin 25mg Tablet is provided in analytical method verification studies while applied formulation is cephradine Capsules. The peak area of standard solution concenteration in analytical method verification studies is approximately 6609294 while the peak area of the standard solution of same concenteration is stability studies is 585429. Clarify the difference in Peak areas.	Submitted The mistake occurred while compiling the empazin tablet dossier and pansef sapsule dossier. The actual area is near about 585429 approx. Thee are difference s because of different in injection volume. The method was verified with actual injection volume.
13.	3.2.P.6	Provide COA of reference standard actually used in the analysis of drug product.	Firm has provided in house working standard COA of Cephradine compacted of batch no. 32052010034
14.	3.2.P.8	The results of batch analysis and stability data reflect that tests of uniformity of dosage units, water contents, dissolution have not been performed throughout stability studies. Justify your stability study data without performance of tests recommended by Pharmacopoeia. Justify the addition of test of pH in stability studies of Cefadroxil capsule which is not present in USP monograph	The dissolution test was performed at each interval of accelerated and real time stability study. USP dissolution parameter were adopted and all the results were found within the specified limit. Firm has not provided revised stability data sheets. pH test was performed as an internal test. The pH test was performed by same method as that

Provide raw data sheets to justify the calculation of results for assay testing at each time point during the the stability testing of each batch.

Submit copy of invoice for evidence of purchase of drug substance used in the development of analysis of each batch of drug product.

Raw data sheets submitted but chromatograms has not been submitted.

Firm has submitted invoice no. 2021042801, dated 28-01-2021, specifying import of 100 kg Cephradine compacted import, duly attested by Assistant Director, DRAP.

Provide copy of BMR for the batches of drug product for which stability studies data is provided in Module 3 section 3.2P.8.3

Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Submitted

As our pharma is new licensee, and we have not came into production. now we have HPLC (Shimadzu 10 AT) which is not 21 CFR Compliance. However we commit that we will soon perform the stability studies on a 21 CFR compliance HPLC system

Decision of 322nd meeting of Registration Board: Deferred the case for following submissions: Data of stability batches supported by attested respective documents like chromatograms, summary data sheets involving the performance of all pharmacopoeial tests.

Submission of the valid copy of GMP Certificate of Drug substance manufacturer.

Submission of fee of Rs. 7,500/- for pre-registration variation (specifications) as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.

Response of firm
Firm has submitted data of stability batches.
Firm has submitted valid GMP Certificate of Drug
substance manufacturer valid till 30-08-2025.
Firm has submitted fee of Rs. 7,500/- for pre-registration
variation (specifications) as per notification No.F.7-
11/2021-B&A/DRAP dated 13-07-2021.

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.

3.	Name, address of Applicant / Marketing Authorization Holder	M/s Alpenglow Pharmaceuticals Plot # A/7 , Export Processing Zone Risalpur, District Nowshera (KP) Pakistan		
	Name, address of Manufacturing site.	M/s Alpenglow Pharmaceuticals Plot # A/7 , Export Processing Zone Risalpur, District Nowshera (KP) Pakistan		
	Status of the applicant	 ☑ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver) 		
	Status of application	☐ New Drug Product (NDP) ☐ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	☑ Domestic sale☐ Export sale☐ Domestic and Export sales		
	Dy. No. and date of submission	Dy. No. 5857 Dated 03-03-2022		
	Details of fee submitted	PKR 30,000/-: Dated 25-01-2022		
	The proposed proprietary name / brand name	PENSEF 125mg/5mL Dry Powder for Suspension		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml after reconstitution contains: Cephradine as Monohydrate 125mg		
	Pharmaceutical form of applied drug	Dry powder for suspension		
	Pharmacotherapeutic Group of (API)	Anti-bacterials for systemic use, First-generation cephalosporins.		
	Reference to Finished product specifications	USP		
	Proposed Pack size	1x12's		
	Proposed unit price	As per SRO		
	The status in reference regulatory authorities	Could not be confirmed.		
	For generic drugs (me-too status)	Velosef 125MG/5MLSuspension		
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.		
	Name and address of API manufacturer.	M/s Zhejiang Anglikang Pharmaceutical Co. Ltd., No. 1000 Shengzhou North Road, Shengzhou, Shaoxing, China.		
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.		
	Module III (Drug Substance)	Official monograph of Cephradine as Monohydrate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and		

	Stability studies Module-III (Drug Product):		justification of specification, reference standard, container closure system and stability studies of drug substance Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (32052010037, 32052010038, 32052010039) 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 equivale dissolution profile	nce and comparative	N/A.	
	Analytical method validation product	ation/verification of	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.	
STABIL	ITY STUDY DATA		•	
Manufac	cturer of API		ikang Pharmaceutical Co. Ltd., No. 1000 Shengzhou zhou, Shaoxing, China.	
API Lot	No.	32052010034		
	ion of Pack er closure system)	60ml HDPE Bottle wi	60ml HDPE Bottle with embossed board unit carton UV coated.	
Stability	Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Per	riod	Real time: 6 months Accelerated: 6 months	Real time: 6 months Accelerated: 6 months	
Frequenc	су	Accelerated: 0, 2, 4, 6 Real Time: 0, 3, 6 (M		
Batch No	0.	001	002	003
Batch Si	ze	1000	1000	1000
Manufac	cturing Date	05-2021	05-2021	05-2021
Date of I	Initiation	28-05-2021	28-05-2021	28-05-2021
No. of B	atches	03		
Adminis	Administrative Portion			
	Reference of previous approval of applications with stability study data of the firm (if any)		The firm has not submitted any document.	
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		ZJ20150108 Date:08-03-2020	

	approval from DRAP (in case of import).		The firm has submitted copy of GMP certificate of M/s Zhejiang Anglikang pharmaceutical Co. Ltd. China issued by China Food and Drug administration. It is valid till 30-08-2020.		
	attested res	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Submitted	
		re Record of HPLC software 21CFR & reports on product testing	Submitt	ed	
		Digital data logger for temperature and nonitoring of stability chambers (real ccelerated)	Submitt	ed	
Remar	ks of Evaluate	or:	•		
Sr.#	Section	Observation		Response of firm	
	1.5.9	Evidence of approval of applied formula (Pensef 125mg/5ml Dry powder for suspension) in reference regulatory autiadopted by Registration Board in 275th meeting shall be submitted.	horities	Firm has not provided evidence. However, product was USFDA approved but discontinued.	
	3.2.S.4.1 Copies of the Drug substance specificat and analytical procedures used for routi testing of the drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacture.		ine g	Firm has submitted USP specifications and Monograph	
	3.2.S.4.3	including specificity, accuracy and repeatability (method precision) perform the Drug Product manufacturer for both compendial as well as non-compendial		Firm has submitted Method Verification studies report encompassing system suitability, Accuracy and recovery, Repaetabilty, intermediate precision and specificity.	
	substance(s) shall be submitted. 3.2.S.4.4 The submitted COAs from both drug substance and drug product manufacture shows that the material used is of companature. Justify the type of drug substance in cephradine suspension since the same used in Capsule dosage form. Provide readable copy of COA performed M/s Alpenglow Pharmaceuticals.		e is	Firm has submitted that Mistakenly the COA of compacted was submitted. The material used in dry suspension is of micronized nature. Firm has submitted COA	
	3.2.S.5			Firm has submitted COA of inhouse working standard for Cephradine (micronized) no. 0023/110/2021,	
	3.2.P.1	P.1 Submit master formulation including theoretical fill weight per bottle alongwidetails of equivalency factor for cephrac monohydrate.		Master formulation including theoretical fill weight per bottle alongwith details of equivalency factor for cephradine monohydrate submitted.	
	3.2.P.2.2.1 Details of applicant and reference product used in pharmaceutical equivalence are required. Submit data of compatibility studies of the drug product with recommended diluent section 3.2.P.2.6.		the	Firm has submitted Pharmaceutical equivalence studies against VELOSEF 250 mg mg/5ml powder for suspension Firm has submitted that compatibility studies involving the	

	Justify the performance of pharmaceutical	reconstitution of Cephradine 250
	equivalence studies with Velosef 250mg / 5ml IV Dry powder injection while applied formulation is dry powder for suspension. Justify why drug release studies / comparative dissolution studies were not performed to justify your formulation development process.	mg/5ml dry suspension using purified water was performed. The Pharmaceutical equivalence studies were performed with velosef dry powder for suspension. This is typographic mistake that velosef injection is mentioned. As the cephradine suspension is formulated as per USP specifications, and neither USP does not defined the test for dissolution of product nor FDA suggests, so the dissolution is not considered in specification of finished product. However in the process of pharmaceutical development comparative dissolution was performed in three
		different medium under in-house set parameters.
3.2.P.5.1	The test for uniformity of dosage unit, deliverable volume and water determination are not added in specifications as recommended in USP monograph. Revise your specifications as per USP monograph along with submission of applicable fee. The assay limits mentioned in specifications are 90% -102% which are different from USP specifications (90%-125%).	Firm has provided Revised specifications of finished product. However, fee for specification revision has not been provided. This is a typographic mistake. Actual limit is 90.0%-125.0%
3.2.P.5.2	Provide detailed method of analysis of the drug product in section 3.2.P.5.2 instead of providing copy of USP monograph.	Submitted
3.2.P.5.3	Provide standard and sample preparation methods used in analytical method verification studies. Justify method verification studies of drug without performance of specificity test. Specify the details of the accuracy test including the details of concentration of 80%, 100% and 120% solutions.	submitted
3.2.P.6	Provide COA of reference standard actually used in the analysis of drug product.	Firm has provided COA of in house working standard of batch no. 0023/110/2021.
3.2.P.8	The results of batch analysis and stability data reflect that tests of uniformity of dosage units, water contents, dissolution have not been performed throughout stability studies. Justify your stability study data without performance of tests recommended by pharmacopoeia. Justify the addition of test of pH in stability studies of cephradine capsule which is not present in USP monograph of applied product. Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch.	The firm has submitted only raw data sheets at different testing time points. However, other information has not been provided.

Submit copy of commercial invoice for evidence of purchase of drug substance that have been used in the development of analysis	
of each batch of drug product.	
Submit compliance Record of HPLC software	
21CFR & audit trail reports on product testing.	

Decision of 322nd meeting of Registration Board: Deferred the case for following submissions:

Evidence of approval of applied formulation in reference regulatory authorities as decided by Registration Board in its 275th meeting.

Submission of valid GMP Certificate of Drug Substance manufacturer.

Data of stability batches supported by attested respective documents like chromatograms, summary data sheets involving the performance of all pharmacopoeial tests.

Submit copy of commercial invoice for evidence of purchase of drug substance that have been used in the development of analysis of each batch of drug product.

Submission of fee of Rs. 7,500/- for pre-registration variation (specifications) as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.

Decision of 322 nd meeting of Registration Board	Response of firm
Evidence of approval of applied formulation in reference	Not submitted
regulatory authorities as decided by Registration Board in	
its 275th meeting.	
Submission of valid GMP Certificate of Drug Substance	
manufacturer.	
Data of stability batches supported by attested respective	
documents like chromatograms, summary data sheets	Submitted
involving the performance of all pharmacopoeial tests.	
Submit copy of commercial invoice for evidence of	
purchase of drug substance that have been used in the	
development of analysis of each batch of drug product.	Submitted
Submission of fee of Rs. 7,500/- for pre-registration	
variation (specifications) as per notification No.F.7-	
11/2021-B&A/DRAP dated 13-07-2021.	Firm has submitted fee of Rs. 7,500/- for pre-registration
	variation (specifications) as per notification No.F.7-
	11/2021-B&A/DRAP dated 13-07-2021(650223749)

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

Registration-II Section

Case No. 01: Decision of USFDA to Withdraw Approval of Makena (Hydroxyprogesterone Caproate Injection) and its Generics

On April, 06, 2023, U.S. Food and Drug Administration announced the final decision to withdraw approval of Makena—a drug that had been approved under the accelerated approval pathway. This drug was approved to reduce the risk of preterm birth in women pregnant with one baby who have a history of spontaneous preterm birth. The decision was issued jointly by the FDA Commissioner and Chief Scientist. Effective today, Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce.

In 2011, FDA approved Makena to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. This accelerated approval was based on a trial that showed the drug reduced deliveries before 37 weeks of pregnancy, an intermediate clinical endpoint that FDA determined was reasonably likely to predict clinical benefit to the newborn.

As a condition of Makena's accelerated approval, the sponsor was required to conduct a confirmatory clinical trial to verify and describe the predicted clinical benefit to newborns. This trial, which was nearly four times larger than the trial that supported Makena's approval, did not show improvement in the health of the babies born to mothers who were treated with Makena. Makena and its generics (i.e., generic versions of Makena) are not shown to be effective for reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Nor have Makena and its generics been shown to be effective for

any subgroup of this population, including in women at high risk of preterm birth. In addition, there are known risks associated with Makena. Accordingly, these drugs do not have benefits that outweigh their risks to patients.

Registration Board while considering the approval of Hydroxyprogesterone Injection in USFDA

registered following drug products.

Sr.	Reg.	Product Name &	Registration Holder /	Renewal Status
No.	No.	Composition	Manufacturer	
1.	096479	Nandrosol 250mg Injection Each ml contains: Hydroxyprogesterone caproate	Pharmasol (Pvt) Ltd, Plot 549, Sunder Industrial estate, Lahore., Lahore	Renewal is not yet due
2.	094205	Hygest Injection Each ml contains: Hydroxyprogesterone caproate	Shaigan Pharmaceuticals (Pvt) Ltd	Renewal is not yet due
3.	003531	Hydroxyprogesterone Injection Each ml contains: Hydroxyprogesterone caproate	M/s. Zafa Pharmaceutical, Karachi.	Renewal is valid
4.	030526	Globinan 2Ml Injection Hydroxy Progesterone Caproate 250mg	Global Pharmaceuticals Pvt Ltd	Renewal Not Submitted
5.	030525	Globinan 1Ml Injection Hydroxy Progesterone	Global Pharmaceuticals Pvt Ltd	Renewal Not Submitted
6.	013624	VIO-DEPOT INJ Each ml contains: Hydroxyprogesterone caproate	Venus Pharma, 23 Km Multan Road Lahore. , Lahore	Renewal Not Submitted
7.	003746	HYDROXYPROGESTRONE INJECTION Each ml contains: Hydroxyprogesterone caproate	Haji Medicines, Rawalpindi	Renewal Not Submitted
8.	003833	HYDROXYPROGESTRONE Each ml contains: Hydroxyprogesterone caproate		Renewal Not Submitted

Following combination drug products containing Hydroxyprogesterone were also registered by the

Registration Board.

Sr.	Reg.	Product Name &	Registration Holder /	Renewal Status
No.	No.	Composition	Manufacturer	
1.	103324	Kevi Injection	Hansel Pharmaceuticals	Renewal is not yet due
		Each ml contains:	(Pvt) Ltd., Plot No 2	
		Hydroxyprogesterone caproate_	Pharma City 30-Km	
		250 mg	Multan Road Lahore. ,	
		Estradiol valerate _ 5 mg	Lahore	
2.	084375	Contrex Injection	Shaigan Pharmaceuticals	Renewal is valid
		Each ml contains:	(Pvt) Ltd	
		Hydroxyprogesterone caproate_		
		250 mg		
		Estradiol valerate _ 5 mg		
3.	077108	Z-Bron Injection	Pharma Health Pakistan	Renewal is valid
		Each ml contains:	(Pvt) Ltd.	
		Hydroxyprogesterone caproate_		
		250 mg		
		Estradiol valerate _ 5 mg		
4.	011155	VIO-DEPOT INJ	Wilson's Pharmaceuticals	Renewal Not Submitted
		HYDROXYPROGESTERONE		
		CARPOATE 250MG		
		QUESTRADIOL VALERATE		
		5MG SESAME OIL 693MG		

5.	000798	GRAVIBINON INJECTION HYDROXY PROGESTERONE CAPROATE 250MG,, OESTRADIOL VALERATE IN OILY SOLUTION	Medipharm (Private) Limited,, 7-A, Gulberg II, Lahore, Lahore	Last renewal was submitted dated 02-10- 2018
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Sub-rule 10 (a) of Rule 30 of Drugs (L, R & A) Rules, 1976 narrates as under:

"(a) if that drug at any time, for safety reasons is withdrawn or banned or certain restrictions are imposed in any of the said countries, then it shall be the responsibility of the manufacturer in Pakistan or as the case may be, the indentors, to immediately withdraw the drug from the market in Pakistan or, as the case may be to impose similar restriction and to inform the registration Board within fourteen days of such an information having come to his knowledge and having taken the necessary action. The Registration Board after getting the said intimation shall take similar action for the same drug available from other sources within the shortest possible time;"

Decision:

Registration Board decided to: -

- i. Recall of Hydroxyprogesterone containing drug product under rule 30 (10) (a) of the Drugs (L, R &A) Rules, 1976 under the Drugs Act, 1976. QA< Division through field force, shall submit data of recalled product to Division of PE&R.
- ii. Issue show-cause notice under section 7(11) (d) read with section 42 of Drug Act 1976/schedule VI of DRAP Act 2012 to all registration holders having valid registration of Hydroxyprogesterone containing drug products.
- iii. Advised RRR Section to proceed for cancellation of registration for Hydroxyprogesterone containing drug product for which renewal was not submitted within due period of time.

Post Registration-II Section

1. M/s Gray's Pharmaceuticals Rawat: Deferred Cases in 316th Meeting of Registration Board.

It is submitted M/s Grays Pharmaceuticals Plot No. 2 Street N-3 National Industrial Zone Rawat has requested for issuance letters of transfer of registration of below mentioned products registered in their name:

Sr.	Reg. No.	Brand Name	Composition
No.			
1.	044218	Graypime 1gm Injection	Each vial contains
			Cefepime (as HCl)1gm
2.	044219	Graypime 500gm Injection	Each vial contains
			Cefepime (as HCl)500gm
3.	044220	Solobect 1gm Injection	Each vial contains:
			Cefoperazone (as Sodium)0.5gm
			Sulbactum (as Sodium)0.5gm
4.	044221	Solobect 2gm Injection	Each vial contains:
			Cefoperazone (as Sodium)1gm
			Sulbactum (as Sodium)1gm
5.	044222	Cephagray 250mg Injection IM/IV	Each vial contains:
			Cephradine with L-Arginine250mg
6.	044223	Cephagray 500mg Injection IM/IV	Each vial contains:
			Cephradine with L-Arginine500mg
7.	044224	Cephagray 1g Injection IM/IV	Each vial contains:
			Cephradine with L-Arginine1g
8.	031929	Medoxin 250mg Injection IM/IV	Each vail contains:
			Cefotaxime (as sodium)250mg
9.	031930	Medoxin 500mg Injection IM/IV	Each vial contains:
			Cefotaxime (as sodium)5000mg
10.	031931	Medoxin 1g Injection IM/IV	Each vial contains:
			Cefotaxime (as sodium)1g
11.	031932	Ne-Zone 250mg Injection IM/IV	Each vial contains:
			Ceftriaxone (as Sodium)250mg
12.	031933	Ne-Zone 500mg Injection IM/IV	Each vial contains:

			Ceftriaxone (as Sodium)500mg
13.	031934	Ne-Zone 1g Injection IM/IV	Each vial contains:
			Ceftriaxone (as Sodium) 1g
14.	063347	Diclogray Injection	Each 3ml contains;
			Diclofenac sodium75mg
15.	063342	Inflacid Injection	Each ml contains
		, and the second	Piroxicam20mg

The firm has submitted following documents:

- a. Copy of minutes of 233rd meeting of Registration Board.
- b. Copies of registration letters
- c. Copies of approvals of contract manufacturing permissions
- d. Submission of fee for transfer of registration
- e. Copies of evidence of submission of renewal applications
- 2. Background of the case is that below mentioned products were registered in name of M/s Gray's Pharmaceuticals Plot No. 442, Street No. 7, I-9/2 Islamabad. Product details with onward approvals are reflected in column VII below:

Sr. No.	Reg. No.	Brand Name	Date of Reg.	Fee submitted	Last renewal details	Remarks:
I	II	III	IV	V	VI	VII
1.	044218	Graypime 1gm Injection Each vial contains Cefepime (as HCl)1gm (USP Specifications) Contract manufacturer: M/s Global Pharmaceuticals Islamabad.	05.10.2006	Rs.8000/-dated 07.05.2012 Rs.12000/- dated: 18.12.2013	29.03.2021 Rs. 10000/-	 Initially registered for contract mfg from M/s Ipram Pharmaceuticals Rawat vide letter No. F.3-5/2006 Reg-II South (M-199) dated 05.10.2006. Approval for extension in contract manufacturing from M/s Global Pharmaceuticals
2.	044219	Graypime 500gm Injection Each vial contains Cefepime (as HCl)500gm (USP Specifications) Contract manufacturer: M/s Global Pharmaceuticals Islamabad.	05.10.2006	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	29.03.2021 Rs. 10000/-	Islamabad vide letter No. F.1-62/2006 Reg-II South dated 19.07.2008 valid till 30.06.2010 Interim extension in contract mfg permission to all manufacturers vide approval No. 6-17/2006-Reg-II (Pt. II) dated 30.06.2010 valid till 31.12.2010 & dated 07.06.2011 till 31.08.2011 & dated 21.09.2011 valid till 31.10.2011
3.	044220	Solobect 1gm Injection Each vial contains: Cefoperazone (as Sodium)0.5gm Sulbactum (as Sodium)0.5gm (USP Specifications) Contract manufacturer: M/s Global Pharmaceuticals Islamabad.	05.10.2006	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	29.03.2021 Rs. 10000/-	
4.	044221	Solobect 2gm Injection Each vial contains: Cefoperazone (as Sodium)1gm Sulbactum (as Sodium)1gm (USP Specifications) Contract manufacturer:	05.10.2006	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	29.03.2021 Rs. 10000/-	

		M/s Global				
		Pharmaceuticals				
		Islamabad.				
5.	044222	Cephagray 250mg Injection IM/IV Each vial contains: Cephradine with L- Arginine250mg Contract manufacturer: M/s Global Pharmaceuticals	05.10.2006	Rs.20000/- dated 02.09.2016	29.03.2021 Rs. 10000/-	 Initially registered for contract mfg from M/s Ipram Pharmaceuticals Rawat vide letter No. F.3-5/2006 Reg-II South (M-199) dated 05.10.2006. Approval for extension in contract manufacturing from
6.	044223	Islamabad. Cephagray 500mg Injection IM/IV Each vial contains: Cephradine with L- Arginine500mg Contract manufacturer: M/s Global Pharmaceuticals Islamabad.	05.10.2006	Rs.20,000/- dated 02.09.2016	29.03.2021 Rs. 10000/-	M/s Global Pharmaceuticals Islamabad vide letter No. F.1- 62/2006 Reg-II South dated 2304.2009 valid till 30.06.2010 • Interim extension in contract mfg permission to all manufacturers vide approval No. 6-17/2006-Reg-II (Pt. II) dated 30.06.2010 valid till 31.12.2010 & dated 07.06.2011 till 31.08.2011 & dated 21.09.2011 valid till 31.10.2011
7.	044224	Cephagray 1g Injection IM/IV Each vial contains: Cephradine with L-Arginine1g Contract manufacturer: M/s Global Pharmaceuticals Islamabad.	05.10.2006	Rs.20,000/- dated 02.09.2016	29.03.2021 Rs. 10000/-	
8.	031929	Medoxin 250mg Injection IM/IV Each vail contains: Cefotaxime (as sodium)250mg Contract manufacturer: M/s Global Pharmaceuticals Islamabad.	10.12.2003	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	15.07.2019 Rs. 10000/-	 Initially registered for contract mfg from M/s Vision Pharmaceuticals Islamabad vide letter No. F.3-3/2003 Reg-II (M-179) dated 10.12.2003. Approval for extension in contract manufacturing from M/s Global Pharmaceuticals Islamabad vide letter No. F.1-62/2006 Reg-II South dated 08.11.2008. Interim extension in contract mfg permission to all manufacturers vide approval No. 6-17/2006-Reg-II (Pt. II) dated 30.06.2010 valid
9.	031930	Medoxin 500mg Injection IM/IV Each vail contains: Cefotaxime (as sodium)500mg Contract manufacturer: Vision Pharmaceuticals Islamabad	10.12.2003	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	15.07.2019 Rs. 10000/-	
10.	031931	Medoxin 1g Injection IM/IV Each vail contains: Cefotaxime (as sodium)1gmg Contract manufacturer: M/s Global Pharmaceuticals Islamabad.	10.12.2003	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	15.07.2019 Rs. 10000/-	till 31.12.2010 & dated 07.06.2011 till 31.08.2011 & dated 21.09.2011 valid till 31.10.2011
11.	031932	Ne-Zone 250mg Injection IM/IV Each vial contains: Ceftriaxone (as Sodium)250mg Contract manufacturer:	10.12.2003	Rs.8000/- dated 07.05.2012 Rs.12000/- dated 18.12.2013	15.07.2019 Rs. 10000/-	

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		M/s Global				
		Pharmaceuticals				
		Islamabad.				
12.	031933	Ne-Zone 500mg Injection	10.12.2003	Rs.8000/-	15.07.2019	
		IM/IV		dated	Rs. 10000/-	
		Each vial contains:		07.05.2012		
		Ceftriaxone (as		Rs.12000/-		
		Sodium)500mg		dated		
		Contract manufacturer:		18.12.2013		
		M/s Global		10.12.2013		
		Pharmaceuticals				
		Islamabad.				
13.	031934	Ne-Zone 1g Injection	10.12.2003	Rs.8000/-	15.07.2019	
13.	031734	IM/IV	10.12.2003	dated	Rs. 10000/-	
		Each vial contains:		07.05.2012	KS. 10000/-	
		Ceftriaxone (as Sodium)		Rs.12000/-		
		*		dated		
		1g Contract manufacturer:		18.12.2013		
		M/s Global		18.12.2015		
		Pharmaceuticals				
	0.622.47	Islamabad.	10.05.2010	20,000/	16062020	
14.	063347	Diclogray Injection	10.06.2010	Rs. 20,000/-	16.06.2020	Both products were registered
		Each 3ml contains;		dated	Rs. 10,000/-	initially to be manufactured by
		Diclofenac		02.09.2016		M/s Global Pharmaceuticals
		sodium75mg				vide Reg letters dated 08th &
		Contract manufacturer:				10 th June, 2010. These
		M/s Global				permissions were valid till
		Pharmaceuticals				30.06.2010.
		Islamabad.				• Interim extension in contract
15.	063342	Inflacid 20mg Injection	08.06.2010	Rs. 20,000/-	16.06.2020	mfg permission to all
		Each ml contains;		dated	Rs. 10,000/-	manufacturers were granted
		Piroxicam20mg		16.11.2015		multiple times which were
		Contract manufacturer:				valid till 31.10.2011.
		M/s Global				
		Pharmaceuticals				
		Islamabad.				

- 2. The firm on 10.10.2011 requested for transfer of registration of above products from existing facility i.e. M/s Grays Pharmaceuticals Plot No. 442 Street No. 7 Sect I-9/s2 Industrial Area Islamabad to their new licensed manufacturing facility i.e. M/s Grays Pharmaceuticals Plot No. 2 Street N-3 National Industrial Zone Rawat, which was granted DML vide approval No. 1-7/2008-Lic dated 22.06.2008. Accordingly, the request of the firm was considered in 233rd meeting of Registration Board held on 15.06.2012 wherein the Board decided to accede the request of for transfer of registrations to M/s Grays Pharmaceuticals Rawat from M/s Grays Pharmaceuticals Islamabad subject to fulfillment of latest fee requirements and confirmation of sections. As per decision of the Board the firm submitted the requisite fee which is reflected in column V above. However, the letter of transfer of registration to new facility couldn't be issued.
- 3. The request of the firm for issuance of transfer letter as per decision of 233rd meeting of Registration Board was discussed in the 316th meeting of the Board held on 15-18th March 2022 firm wherein it was deferred for submission of evidence regarding submission of applications for extension in contract manufacturing permission up to year 2012 and subsequent renewals after year 2012.
- 4. The last renewal submission evidence details are recorded in the last column VI above as required by the Board in 316th meeting. Hence as per aforementioned renewal submissions, the renewal application for products at Sr. No. 1-7 are within time but the renewal submission for products at Sr. No. 8-15 are submitted after due date but within one year, therefore differential fee is required under SRO 1005(I)/2017.

Decision of 327th meeting of Registration Board:

The Board deliberated the matter at length. Considering the facts narrated above, the Board decided to cancel the above registrations in name of existing facility i.e., M/s Gray's Pharmaceuticals, Plot No. 442, Street No. 7, Sector I-9/2, Industrial Area Islamabad (DML No. 000518) and grant them in name of new licensed manufacturing facility i.e M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3, National Industrial Zone Rawat (DML No. 000518)

by way of self manufacturing, subject to confirmation of renewal status under Rule 27 of the Drugs (LR&A) Rules 1976 amended vide SRO 1005(I)/2017 dated 05.10.2017. The firm shall also submit the fee if required under the afore said provisions.

Export Facilitation Desk

Case No.01: Registration of Drug (s) of M/s Swiss Pharmaceuticals (Pvt.) Ltd, A/159, S.I.T.E. Super Highway, Karachi for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form 5;
Copy of DML (Renewal status) along with approval of	Copy of DML provided
relevant sections verified by licensing Division or	Approval of relevant section verified from Inspection
inspection report for renewal of DML before 2005.	renewal of DML dated 30-12-2014
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of
	DML dated 06-07-2021
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.	Vonzap 10/100mg Tablet	Purchase order from Sri	Dy. No. 166(09.03.2023)
	Each delayed release tablet contains:	Lanka	Rs.75,000/- (16.12.2022)
	Aspirin100mg	Cabpirin film coated	
	Vonoprazan fumarate eq to vonoprazan10mg	tablet are PMDA Japan	
		approved. Firm has	
		applied delayed release	
		tablet.	

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

Case No.02: Registration of Drug (s) of M/s Fast Pharmaceuticals (Pvt.) Ltd, Plot No. 55, Street No. S-4, National Industrial Zone, Rawat, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per	Form 5;
relevant SRO.	
Copy of DML (Renewal status) along with approval of	Copy of DML provided
relevant sections verified by licensing Division or	Approval of relevant section verified from letter No. Nil
inspection report for renewal of DML before 2005.	dated 29-04-2022
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of
	DML dated 28-02-2022
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
Ι	II	III	IV

1.	Premac-N 75mg/1500mcg/10mg Tablets	Purchase order from	Dy. No. 183(10.03.2023)
	Each film coated tablet contains:	Afghanistan	Rs.75,000/- (07.03.2023)
	Pregablin (SR)75mg		
	Methycobalamin1500mcg		
	Nortriptyline (as HCl)10mg		
2.	Minalin 75mg/1500mcg Tablets	Purchase order from	Dy. No. 198(15.03.2023)
	Each film coated tablet contains:	Afghanistan	Rs.75,000/- (28.02.2023)
	Pregabalin (SR)75mg		
	Methycobalamin1500mcg		
3.	Diser 100mg/20mg Tablets	Purchase order from	Dy. No. 199(15.03.2023)
	Each modified release tablet contains:	Afghanistan	Rs.75,000/- (07.03.2023)
	Diclofenac sodium (as enteric coated		
	core)100mg		
	Serratiopeptidase (as immediate release		
	coat)20mg		
4.	Diser 50mg/10mg Tablets	Purchase order from	Dy. No. 200(15.03.2023)
	Each modified release tablet contains:	Afghanistan	Rs.75,000/- (07.03.2023)
	Diclofenac sodium (as enteric coated core)50mg		
	Serratiopeptidase (as immediate release		
	coat)10mg		
5.	Apser 100mg/325mg/10mg Tablets	Purchase order from	Dy. No. 201(15.03.2023)
	Each tablet contains:	Afghanistan	Rs.75,000/- (07.03.2023)
	Aceclofenac100mg		
	Paracetamol325mg		
	Serratiopeptidase10mg		

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

Case No.03: Registration of Drug (s) of M/s Wnsfeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of	Copy of DML provided
relevant sections verified by licensing Division or	Approval of relevant section verified from Inspection report
inspection report for renewal of DML before 2005.	cGMP dated 10-12-2020
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on
	inspection dated 10-12-2020
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
	Bio-Alaxin Suspension	Purchase order from	Dy. No. 8869/22
1	Each 80ml of reconstituted suspension contains:	Myanmar	(24.01.2023)
1	Dihydroartemisinin80mg		Rs.75,000/- (11.01.2023)
	Piperaquine Phosphate640mg		

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

Case No.04: Registration of Drug (s) of M/s Rock Pharmaceuticals Laboratories (Pvt.) Ltd, Plot No. 134-B & 135-B, Nowshera Industrial Estate Risalpur, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as	Form5;
per relevant SRO.	
Copy of DML (Renewal status) along with approval of	Copy of DML provided
relevant sections verified by licensing Division or	Approval of relevant section verified from letter No. F 3-
inspection report for renewal of DML before 2005.	1/98-Lic dated 15-11-2021
GMP Status. Copy of Inspection report/GMP	GMP status verified from GMP certificate based / on
certificate.	inspection dated 22-11-2022
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 Statu	us	Dy.No.(EFD)/Fee with
					date
I	II		III		IV
	New Veribion Tablet	Purc	chase order from		v. No. 238/23 (30.03.2023)
	Each film coated tablet contains:	Nige	eria	Rs	.75,000/- (22.03.2023)
	Thiamine mononitrate U.S.P10mg				
1	Pyridoxine Hydrochloride U.S.P3mg				
	Cyanocobalamin U.S.P15mcg				
	Niacinamide USP45mg				
	Calcium Pantothenate5mg				

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

Case No.05: Registration of Drug (s) of M/s Nabi Qasim Industries (Pvt.) Ltd, 17/24, Korangi Industrial Area, Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Form5; Graph Copy of DML provided Approval of relevant section verified from letter No. F
Approval of relevant section verified from letter No. F
**
2-20/85-Lic dated 27-04-2020
GMP status verified from GMP certificate based / on
inspection dated 27-05-2022
r Provided
(

Suxamethonium chloride 100 mg/2 ml is approved by MHRA of UK as liquid injection.

Detail of the products is given below:

	tun 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	Succinab Lyophilized Powder for solution for I.M / I.V Injection 200mg Each vial contains: Suxamethonium chloride BP200mg	Purchase order from Uganda	Dy. No. 239/23 (30.03.2023) Rs. 75,000/- (13.03.2023)
2	Succinab Lyophilized Powder for solution for I.M / I.V Injection 100mg	Purchase order from Uganda	Dy. No. 240/23 (30.03.2023) Rs. 75,000/- (13.03.2023)

Each vial contains:	
Suxamethonium chloride BP	00mg

Decision: Registration board while considering the purchase order from the importing country i.e., Uganda decided to approve the applied products of Succinab Lyophilized Powder (Suxamethonium chloride) for solution for I.M / I.V Injection 200mg & Succinab Lyophilized Powder (Suxamethonium chloride) for solution for I.M / I.V Injection 100mg for export only for Uganda.

$Registration \ of \ Drug \ (s) \ of \ M/s \ Sami \ Pharmaceuticals \ (Pvt.) \ Ltd, F-95, Off \ Hub \ River$ Case No.06: **Road, S.I.T.E. Karachi, for export purposes only.** Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form 5;
Copy of DML (Renewal status) along with approval of	Copy of DML provided
relevant sections verified by licensing Division or	Approval of relevant section verified from letter No. F
inspection report for renewal of DML before 2005.	2-9/2007-Lic dated 22-06-2018
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on
	inspection dated 17-11-2022
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 are given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with
I	II	III	date IV
1	PREGNO NEW MOM Tablets Each film coated tablet contains: 100 mg Hydrolyzed Marine Collagen 100 mg Silica 10 mg Citrus Bioflavonoids 7.5 mg Co-Q10 5 mg Grape Seed Extract 7.5 mg L-Methionine 15 mg L-Cysteine 15 mg Beta Carotene 1 mg VitaminD3 5mcg (200 IU) Vitamin E 20 mg α-TE Vitamin C 40 mg Thiamine (Vitamin B1) 4 mg Riboflavin (Vitamin B2) 2 mg Niacin (Vitamin B3) 9 mg NE Vitamin B6 4 mg Folic Acid 200 mcg Vitamin B12 10 mcg Biotin 75 mcg Pantothenic Acid 20mg Calcium 200 mg Magnesium 37.5 mg Copper 500 mcg Manganese 0.25 mg Selenium 50 mcg Chromium 20 mcg Iodine 75 mcg<	Purchase order from Afghanistan Similar product of Vitabiotic UK is enlisted by H&OTC Division as imported product.	Dy. No. 241/23 (30.03.2023) Rs. 75,000/- (07.11.2022)
2	PREGNO COMPLETE Tablets Each film coated tablet contains: Vitamin D3. 10 mcg (400IU) Vitamin E. 4mg α-TE Vitamin K. 70mcg Vitamin C. 70mg Thiamin (Vitamin B1). 3mg Riboflavin (Vitamin B2). 2mg	Purchase order from Afghanistan Similar product of Vitabiotic UK is enlisted by H&OTC Division as imported product.	Dy. No. 242/23 (30.03.2023) Rs. 75,000/- (07.11.2022)

	Niacin (Vitamin B3)20mg NE		
	Vitamin B610mg		
	Folic Acid400mcg		
	Vitamin B126mcg		
	Biotin150mcg		
	Pantothenic Acid6mg		
	Magnesium150mg		
	Iron17mg		
	Zinc		
	Copper		
	Selenium30mcg		
	Iodine		
	Beta Carotene2mg		
3	PREGNO PRE-CONCEPTION Tablets	Dunch as and an from	Dr. No. 242/22
3		Purchase order from	Dy. No. 243/23
	Each film coated tablet contains:	Afghanistan	(30.03.2023)
	L-Arginine100mg		Rs. 75,000/- (04.11.2022)
	Inositol50mg	Similar product of	
	N-Acetyl Cysteine50mg	Vitabiotic UK is	
	Beta Carotene3mg	enlisted by H&OTC	
	Vitamin D ₃ 15mcg (600 IU)	Division as imported	
	Vitamin E4mg α-TE	product.	
	Vitamin C90mg		
	Thiamin (Vitamin B1)8mg		
	Riboflavin (Vitamin B2)5mg		
	Niacin (Vitamin B3)20mg		
	Vitamin B610mg		
	Folic Acid400mcg		
	Vitamin B1220mcg		
	Biotin150mcg		
	Pantothenic Acid6mg		
	Magnesium		
	Iron		
	Zinc		
	Copper		
	Selenium		
	8		
4	Iodine	Dunch one order from	Dv. No. 244/22
4	OSTIFLEX Tablets	Purchase order from	Dy. No. 244/23
	Each film coated tablet contains:	Afghanistan	(30.03.2023)
	Glucosamine Sulphate KCl250 mg	G: 11 1 2	Rs. 75,000/- (04.11.2022)
	Chondroitin Sulphate	Similar product of	
	Ginger Root equivalent to (from extract)25mg	Vitabiotic UK is	
	Vitamin D38.33 mcg (333.2 IU)	enlisted by H&OTC	
	Vitamin C	Division as imported	
	Calcium	product.	
	Magnesium50mg		
	Zinc5 mg		
	Copper333.33 mcg		
	Manganese0.16mg		
	Selenium		
<u> </u>	~	1	l .

Decision: The Board deliberated the matter and decided that the firm shall apply in division of Health & OTC for export enlistment of their products.

Case No. 01: Registration of Drugs under the Drugs Act, 1976-Virtual Inspection Reports of Manufacturer Abroad.

Following veterinary products approved in 291st meeting of Registration Board subject to inspection of manufacturer abroad as per import policy.

S.	Name of Importer/	Name of Drug/ Composition	Panel of Inspector(s)/ Date
No.	Manufacturer	& meeting number	of inspection
1.	M/s. Uranus Bio-Tech	(i) Albentong Sus 10 Oral	(i)Mr. Abdullah Abro,
	Private Limited. Office #	Suspension	Deputy Director (MD&MC),
	112, 1 st Floor, Arooj	Each ml contains:-	DRAP, Islamabad.
	Arcade, F10 Markaz,	Albendazole100mg	
	Islamabad, Pakistan		(ii)Malik Muhammad Asad,
	Manufacturer:-	(ii) Ivertong 1% Injection	Deputy Director (Pharmacy
	M/s. Chongqing Fangtong	Each ml contains:	Services), DRAP,
	Animal Pharmaceutical	Ivermectin10mg	Islamabad.
	Co. Ltd. No. 80, East Part		
	of Chan gzhou Road,	(iii) Flortong 30 Injection	16 ^h & 20 th December, 2022
	Rongchang District,	Each ml contains:	
	Chongqing, China.	Florfenicol300mg	
		(M-291)	

Accordingly, an inspection was carried out by inspection panel dated 16^h & 20th December, 2022 and final remarks of the panel are as under:-

Conclusion:

Based on the proceedings of virtual inspection, documents reviewed and videos of the unit seen, the panel has reached to the conclusion that the firm has basic systems to manufacture veterinary drugs and appeared to comply the GMP requirements. Hence, the panel recommends that the Registration Board may grant the registration of applied products namely Albentong Sus 10 Oral Suspension (Albendazole ...100mg) in 100ml plastic bottle, Flortong 30 Injection (Florfenicol300mg) in 100ml vial & Ivertong 1% Injection (Ivermectin....10mg) in 10ml vial to M/s. Uranus Bio-Tech Private Limited, Islamabad. 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/in-person inspection.

Decision: Decision: Registration Board deliberated the matter and decided to remand back the case to inspecting panel for clear and candid recommendations. The division shall process the case before issuance of minutes of the meeting.

Case No. 02: Registration of Drugs under the Drugs Act, 1976-Virtual Inspection Reports of Manufacturer Abroad.

Following veterinary products approved in 308th meeting of Registration Board subject to inspection of manufacturer abroad as per import policy.

S.	Name of Importer/	Name of Drug/ Composition/	Panel of Inspector(s)/
No.	Manufacturer &		Date of inspection
	meeting number		

	T		
1.	M/s. Medicinia	(i) Amoclave Tablet 375mg	(i)Mr. Abdullah Abro,
	Corporation,	Each film coated tablet contains:-	Deputy Director
	234, Sunny Plaza, Hasrat	Amoxicillin as Trihydrate250mg	(Controlled Drugs),
	Mohani Road, Karachi. /	Potassium Clavulanate as Clavulanic	DRAP, Islamabad.
	Manufacturer &	Acid125mg	
	Marketing Authorization	_	(ii)Mr. Muhammad
	Holder:- M/s. Reyoung	(ii) Amoclave Tablet 625mg	Kashif,
	Pharmaceutical Co.,	Each film coated tablet contains:-	Deputy Director
	Ltd., No.1, Ruiyang	Amoxicillin as	(Biological), DRAP,
	Road, Yiyuan County,	Trihydrate500mg	Islamabad.
	Shandong Province,	Potassium Clavulanate as Clavulanic	
	China.	Acid125mg	
			13 ^h & 14 th February,
		(iii) Amoclave Tablet 1000mg	2023
		Each film coated tablet contains:-	
		Amoxicillin as	
		Trihydrate875mg	
		Clavulanic Acid as Potassium	
		Clavulanate125mg	
		5	
		(M-308)	

Accordingly, an inspection was carried out by inspection panel dated 13^h & 14th February, 2023 and final remarks of the panel are as under:-

Conclusion & Recommendations:

Based on the proceedings of virtual inspection, documents reviewed and videos of the unit seen, the panel has reached to the conclusion that the firm has basic systems to manufacture tablets and appeared to comply the cGMP requirements. Hence, the panel recommends that the registration of the applied products namely registration of applied products namely Amoclave Tablet (375mg,625 and 1000mg) may be granted to M/s. Medicinia Corporation, 234, Sunny Plaza, Hasrat Mohani Road, Karachi Karachi,

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/in-person inspection.

Decision: Registration Board deliberated the matter and decided to remand back the case to inspecting panel for clear and candid recommendations. The division shall process the case before issuance of minutes of the meeting

Case No. 03: Request of M/s Selmore Pharmaceuticals Pvt. Ltd. for grant pack size of Redycef RTU Injection (Ceftiofur as hydrochloride):

2.	Name and address of manufacturer /	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan		
	Applicant	Road, Lahore.		
	Brand Name +Dosage Form +	Redycef RTU Injection 10ml		
	Strength			
	Composition Each ml contains:-			
	Ceftiofur as hydrochloride 50mg			
	Diary No. Date of R& I & fee	Rs.30,000/- (20986/26.07.2022)		
	Pharmacological Group	Cephalosporin antibiotic		
	Type of Form	Form-5		
	Finished product Specification	Innovators Specification		
	Pack size & Demanded Price	10ml / Decontrolled		
	Me-too status	CEFUR-RTU Injection, Registration No: 049605.		
		by M/s. Nawan Laboratories Pvt. Ltd. Karachi, Pakistan		
	GMP status	New Section Approval granted on 04-07-2022		

Remarks of the Evaluator.	Me-too granted 50,100ml
Decision of 323 rd meeting: Approved	with innovator's specifications.

Remarks: - Firm submitted 10ml pack sizes of same formulation of M/s. Nawan Laboratories (Pvt) Ltd., Karachi & M/s. S.J & G Fazul Elahi (Pvt) Ltd., Karachi.

M/s Selmore requested for grant of 10ml or 20ml as already granted (Reg. 063704, EXCEFUR INJECTION) to M/s. S.J & G Fazul Elahi (Pvt) Ltd., Karachi.

Decision: Registration Board deliberated the matter in detail and decided as under:

- i. Acceeded to the request of M/s Selmore Pharmaceuticals for grant of 20ml pack size and firm will submit full fee for change in pack size.
- ii. Registration Board directed to Additional Director Karachi for confirmation of Ceftiofur 10ml Injection approval and manufacturing of Ceftiofur 10ml Injection of both firms i.e. M/s. Nawan Laboratories (Pvt) Ltd., Karachi & M/s. S.J & G Fazul Elahi (Pvt) Ltd., Karachi and submit the report to Chairman Registration Board/Director PE&R Division.

Import & Vet-II Section

Case No: 01 REQUEST OF M/S AMTUL PHARMACEUTICALS, LAHORE REGISTRATION OF DRUGS (OMULCER 40MG INJECTION) UNDER THE DRUGS ACT, 1976.

The subject case was discussed in 320th meeting of Registration Board as under: -

Registration Board in its 261st meeting approved the following product of M/s. Amtul Pharmaceuticals, Lahore as per decision mentioned alongside each;

Importer M/s. Amtul	Omulcer 40mg Injection	Pack size	Approved as per
Pharmaceuticals, 251-Sikandar	Each vial of lyophilized	one vial	Import Policy for
Block Allama Iqbal Town,	powder	Rs. 750/-	Finished Drugs.
Lahore	contains:-		
Manufacturer:	Omeprazole Sodium 40mg		
M/s Reyoung	Proton Pump Inhibitior		
Pharmaceutical Co.No.6,	Specifications:-		
Erlangshan Road, Yiyuan	Manufacturer		
County, Shandong			
Province, P.R. China.			
Priority # 85			

Now, M/s AMB HK Enterprises (Pvt) Ltd, Lahore has submitted request for registration of above product on their name and submitted following documents: -

- Original cancellation letter from REYOUNGE to M/s Amtul Pharmaceuticals, Lahore.
- Original agreement of REYOUNGE with M/s AMB HK Enterprises (Pvt) Ltd, Lahore.
- Original CoPP for Omeprazole 40mg Injection.

In view of above, a letter vide No.F.1-8/2020-I&V-II/Human Import dated 31st May, 2022 & reminder for the same dated 24th August, 2022 was conveyed to the firm and advised to submit fresh sole agency agreement letter in your name from product license holder and no reply from the M/s Amtul Pharmaceuticals, Lahore received.

Decision M-320: Registration Board considered the case and decided to issue a reminder to M/s. Amtul Pharmaceuticals, Lahore for submission of fresh sole agency agreement letter in their name form product license holder.

Proceedings of 327th **meeting:** The Board was apprised that M/s Amtul Pharmaceuticals had not submitted requisite documents as per decision of 261st meeting of Registration Board wherein the application was decided as "Approved as per Import Policy for Finished Drugs". The Board was further apprised that a reminder was issued to M/s Amtul Pharmaceuticals for submission of fresh sole agency agreement letter in their name from product license holder as per decision of 320th meeting of Board but

till date the firm has failed to submit required documents.

Decision: Registration Board while considering the above cited facts decided to withdraw the approval of 261st meeting in name of M/s. Amtul Pharmaceuticals, 251-Sikandar Block Allama Iqbal Town, Lahore for the "Omulcer 40mg Injection" and directed the I&V-II section for evaluation of M/s AMB HK Enterprises (Pvt) Ltd, Lahore application.

Case No: 02 M/S SANOFI-AVENTIS PAKISTAN REQUESTED FOR EXTENSION IN EXEMPTION FROM LABELING TEXT ON – GLUCANTIME 1.5G/5ML SOLUTION FOR INJECTION (REG. NO.088889)

M/s Sanofi-aventis Pakistan Limited, Plot No. 23, Sector No. 22, Korangi Industrial Area, Karachi has requested that subject product is being manufactured and primarily packaged in large volume at the source point from where it will be exported / distributed to different countries as per their needs.

In light of the above, the firm requested for extension in labeling exemption of the said product and product import in Standard Export Packs and <u>locally print the Registration Number, Maximum Retail Price and Urdu Text on the packs once imported</u> at their licensed premises i.e. M/s Sanofiaventis Pakistan Limited, Plot No. 23, Sector No. 22, Korangi Industrial Area, Karachi (Drug Manufacturing License No.000007 by way of formulation)

Previously competent authority has granted permission on 15th March, 2021on the same subject mentioned as above.

Firm has submitted following supporting documents: -

- 1. A requisite fee Rs.10,000/-.
- 2. Copy of registration letter (issued on 17th May, 2018)
- 3. Copy of previous approval for Urdu labeling exemption.
- 4. SOP's for "Control of repacking operations"
- 5. An undertaking.

Decision: Registration Board acceded to the request of firm for extension in labeling exemption of the GLUCANTIME 1.5G/5ML SOLUTION FOR INJECTION (REG. NO.088889) to be imported in Standard Export Packs and locally print the Registration Number, Maximum Retail Price and Urdu Text on the packs once imported at their licensed premises i.e. M/s Sanofiaventis Pakistan Limited, Plot No. 23, Sector No. 22, Korangi Industrial Area, Karachi (Drug Manufacturing License No.000007 by way of formulation) to comply with the requirements as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for two (02) year only. The firm shall submit the future plan regarding the import of Drugs (Labelling & Packing) Rules, 1986 compliant packs.

Case No. 1 Renewal applications referred to Registration Board by Renewal Sub Committee

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
M/s. N	Medera Phar	maceuticals (Pvt) Ltd.,Plot No.2, S	treet N-4 National	Industrial Zone Ra	iwat.
1.	087360	Tazonem Injection 2g/250mg Each vial contains Piperacillin (as sodium) 2gm Tazobactam (as sodium)250 mg (USP Specifications) Contract Manufacturer: M/s. Global Pharmaceuticals (Pvt) Ltd, Plot No.22-23, Industrial Triangle Kahuta Road, Islamabad.	03/01/2018	Dy. No.246 dated 03/01/2023 Rs.75000/- Dy. No. 8390 dated 27.03.2023 Rs. 75000/-	Renewal is granted w.e.f 03.01.2023 to 02.01.2028.
2.	087359	Tazonem Injection 4g/500mg Each vial contains Piperacillin (as sodium)4 gm Tazobactam (as sodium)500 mg (USP specifications) Contract Manufacturer: M/s. Global Pharmaceuticals (Pvt) Ltd, Plot No.22-23, Industrial Triangle Kahuta Road, Islamabad.	03/01/2018	Dy. No.246 dated 03/01/2023 Rs.75000/- Dy. No. 8390 dated 27.03.2023 Rs. 75000/-	Renewal is granted w.e.f 03.01.2023 to 02.01.2028.

Remarks:

The application was deferred in 8th meeting of Renewal Sub Committee for submission of differential fee Rs. 75000/-as renewal application is submitted after due date but within sixty days. The firm has now submitted the fee which is recorded above.

Decision of the Board is mentioned against each case.

M/s, F	M/s. Helix Pharma (Pvt) Ltd., A/56 SITE Mangopir Karachi.(DML No.000030)						
3.	028931	Tycef Capsule	13/08/2002	Rs: 10000/- dated	Deferred for opinion		
		Each capsule contains:		25.04.2022	of Legal Affairs		
		Cefixime USP400mg	Approval of	Rs: 75000/- dated	Division.		
		_	contract Mfg:	25.04.2022			
		Manufacturer:	24.11.2020	Rs.75000/-			
		M/s. Opal Laboratories (Pvt)	Valid till:	dated 29.07.2022			
		Ltd., LC/41 SITE Landhi	23.03.2022				
		Karachi.					
4.	028165	Tycef Paediatric Suspension	10/08/2002	Rs: 10000/- dated	Deferred for opinion		
		Each 5ml contains:		25.04.2022	of Legal Affairs		
		Cefixime USP100mg	Approval of	Rs: 75000/- dated	Division.		
		Manufacturer:	contract Mfg:	25.04.2022			
		M/s. Opal Laboratories (Pvt)	24.11.2020	Rs.75000/-			
		Ltd., LC/41 SITE Landhi	Valid till:	dated 29.07.2022			
		Karachi.	23.03.2022				

5.	048552	Tycef DS Suspension	20/03/2008	Rs: 10000/- dated	Deferred for opinion
		Each 5ml contains:		25.04.2022	of Legal Affairs
		Cefixime Trihydrate eq. to	Approval of	Rs: 75000/- dated	Division.
		Cefixime200mg	contract Mfg:	25.04.2022	
		Manufacturer:	24.11.2020	Rs.75000/-	
		M/s. Opal Laboratories (Pvt)	Valid till:	dated 29.07.2022	
		Ltd., LC/41 SITE Landhi	23.03.2022		
		Karachi.			

Remarks of RRR section in 8th Sub Committee:

The firm was given an approval of contract manufacturing from M/s. Opal Laboratories (Pvt) Ltd., LC/41 SITE Landhi Karachi for period of sixteen months i.e. till 23.03.2022 vide DRAP approval F.296-RB/2020 (PR-I) dated 24.11.2020 with the advice to submit quarterly progress on the activities undertaken by the firm in 296th meeting. Details are as under:

Phase 1: Renovation of general packaging area (tablets and capsules) will be completed by Dec-2020

Phase II: Renovation of blistering, coating &encapsulation will be completed by May 2021.

Phase III: Renovation of Dry Suspension, blending, granulation and packaging will be completed by November 2021

Phase IV: Renovation of liquid manufacturing, filling and packing will be completed by March 2022.

Phase V: Renovation of oral cephalosporin (capsule and dry powder suspension) will be completed by Feb,2022.

However instead of submitting the progress report the firm has submitted extension application. GMP inspection conducted by area FID dated 29.06.2022 wherein the GMP was rated as GOOD. Section approval letters vide letter No.F.2-1/2003-Lic Vol-II dated 21st June, 2021 indicating Dry Powder Suspension (Cephalosporin).

Decision of Renewal Sub Committee and Reply:

The application was deferred in 8th meeting of Renewal Sub Committee for submission of progress report as per undertaking in 296th meeting of Registration Board. In response to the above decision of the Committee the firm submitted reply vide Dy. No. 8391 dated 27.03.2023 wherein they have submitted that we have applied for withdrawal of Cephalosporin section due to non-feasibility for manufacturing of cephalosporin registered products & DRAP–Licensing section issued letter No. F.2-20/84-Lic (Vol-V), dated:23rd Oct, 2020 for withdrawal of Cephalosporin section is enclosed herewith for your kind perusal. Initially we have applied for contract manufacturing for our above registered products on basis of renovation /upgrade Cephalosporin area but later on we have withdrawn Cephalosporin section as mentioned above. Kindly consider our submitted application for renewal of Contract manufacturing along with fee of our registered Cephalosporin products & grant us the Contract Manufacturing for 05 years at your earliest on basis of withdrawal of Cephalosporin area.

Decision of the Board is mentioned against each case.

M/s.	Amgomed O	office No.04, 1st Floor, Ghousia Plaz	a Main Jinnah Blu	e Area Islamabad.	
M/s. 6.	Amgomed O 053821	Amgozole infusion 40mg Each vial contains: Omeprazole as sodium40mg Manufacturer: M/s Biolabs Pvt Limited Plot No. 145 Industrial triangle Kahuta Road Islamabad.	Transfer of reg. from Import to local: 19.01.2015	Rs. 50000/- dated; 18.03.2020 Dy. No. 32110 dated 07.11.2022 Rs.75000/-	Keeping in view the opinion of Legal Affairs Division, Registration Board granted renewal of registration w.e.f. 19.01.2020 to 18.01.2025. The firm shall apply for the change of
					address as per Drug sale license in the concerned section and after approval o the aforesaid change the renewal lette shall be issued.

Extension in contract manufacturing was extended for next five years vide DRAP letter No. F.8-2/2015-Reg-III (M-248) dated 27.08.2015 w.e.f. **19.01.2015**.

Approval of change of address from M/s Amgomed Office No. 5 1st floor Rose Plaza I-8 Markaz Islamabad to M/s Amgomed Office No. 4, 1st Floor Ghousia Plaza Jinnah Avenue Blue Rea Islamabad is required.

Panel inspection of M/s Biolabs Pvt Limited Plot No. 145 Industrial triangle Kahuta Road Islamabad dated 08.07.2021, 15.07.2021, 30.07.2021 and 03.08.2021 recommends renewal of DML and indicates Dry Powder Injection (General).

Decision of Renewal Sub Committee and Reply:

The application was deferred in 7th meeting of Renewal Sub Committee for opinion of Legal Affairs Disvion that whether application can be considered under Rule 27 of Drug (LR&A) Rules 1976 as application for extension in contract manufacturing was received after due date under the former contract manufacturing policy. The Disvion has now opined on the matter which is reproduced as under:

It is submitted that the subject cases have been evaluated in the light of latest Contract Manufacturing Policy and Rule 27 of the Drugs (LRA), Rules, 1976. Rule 27 of the Drugs (LRA) Rules, 1976 provides as follows: Chapter,

"27. Duration of certificate of registration. A certificate of registration under this shall unless earlier suspended or cancelled, be in force for a period of five years from the date of Registration of the drug and may thereafter be renewed for periods not exceeding five years and a certificate to this effect shall be issued within one month at a time. Provided that an application shall be made within Sixty days after the expiry of the registration and when an application has been made as aforesaid the registration shall subject to the orders passed on the application for the renewal continue in force for the next period of five years"

Moreover, in SRO 1347(I)/2021 (Contract Manufacturing Policy) the effects of Rule 27 shall mutatis mutandis applicable. Hence, in both instant cases, the fee was submitted well within period of 60 days after the expiry of the registration and fall in proviso clause of rule 27.

Moreover, the registration was granted to both the firms as per previous contract manufacturing policy and expired during enforcement of the previous policy. However, during the pendency of the renewal application, new contract manufacturing Policy promulgated on 15th October, 2021 vide SRO 1347(I)/2021. It is settled law that if during pendency of any application, the law/policy has been amended or changed then the pending application shall be processed in accordance with amended or new law/policy. Reliance is placed on judgment dated 11.05.2022 in CP No. 4425/2021 M/s Medisure Laboratories Vs FOP by Sindh High Court, Karachi. Therefore, in the light of above facts and position of the law, the applications of the firms may be processed accordingly.

Decision of the Board is mentioned against each case.

M/s Laderley Bio-Tech Pharma 240 Street 6, Phase 2 Gulraiz Colony Rawalpindi.						
7.	072568	Zoletech Inj 40mg	13.06.2013	Rs.50000/-dated	Keeping in view the	
		Each vial (lyophilized)contains	Approval of	15.04.2021	opinion of Legal	
	Omeprazole Sodium 4.6mg eq to import to local		Affairs Division,			
		40mg	Mfg:		Registration Board	
		Contract Manufacturer:	07.04.2016		granted renewal of	
		M/s Biolabs Pvt Limited Plot No.			registration w.e.f	
		145 Industrial triangle Kahuta			07.04.2021 to	
		Road Islamabad.			06.04.2026	

Decision of Renewal Sub Committee and Reply:

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Decision of the Board is mentioned against each case.

Case No: 2 Renewal applications submitted after due date but within sixty days

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration	Date of application (R&I) Fee submitted	Decision	
			PRV (If any)			
	M/s. Frontier Dextrose Limited, Plot No. 18/3 Phase-I Hattar Industrial Estate Hattar(DML No.000633)					
8.	003774- EX	FDL-DS 1/2 Infusion Each 100ml contains: Dextrose Anhydrous B.P5gm Sodium Chloride0.45gm Water for injectionQS	16-10-2012	Dy. No. 34879 dated 01-12-2022 Rs. 30000/-	Renewal is granted w.e.f 16.10.2022 to 15.10.2027	
9.	003776- EX	FDL Ringer's (Infusion) Each 1000ml contains: Sodium Lactate3.10gm Calcium Chloride dihydrate0.27gm Potassium Chloride0.40gm Sodium Chloride6gm Water for Injectionq.s to make 1000ml	16-10-2012	Dy. No. 34880 dated 01-12-2022 Rs. 30000/-	Renewal is granted w.e.f 16.10.2022 to 15.10.2027	
10.	049818	Sterifluid-5 Infusion Each 100ml Contains: Dextrose Monohydrate eq. to Anhydrous Dextrose5gm. (B.P Specs)	16-07-2008 Change of BN: 24.09.2008	Rs.10000/- dated 26.08.2013 Rs. 10000/- dated 16.07.2018 Dy. No. 1268 dated 13.01.2023 Rs.20000/- dated 10.01.2023 (Slip No.5264618291) Rs. 20000/- (Slip No.5709069592)	Renewal is granted w.e.f 16.07.2018 to 15.07.2023	
11.	049819	Sterifluid-10 Infusion Each 100ml Contains:- Dextrose Monohydrate eq. to Anhydrous Dextrose	16-07-2008 Change of BN: 24.09.2008	Rs.10000/- dated 26.08.2013 Rs. 10000/- dated 16.07.2018 Dy. No. 1268 dated 13.01.2023 Rs.20000/-	Renewal is granted w.e.f 16.07.2018 to 15.07.2023	

	1	T			T
	0.15.7.7.7			dated 10.01.2023 (Slip No.63229266) Rs. 20000/- (Slip No.9998827102)	
12.	049285	Sterifluid-DS 1/2 Infusion Each 100ml Contains Dextrose Monohydrate eq. to Anhydrous Dextrose5gm Sodium Chloride0.45gm (B.P Specs)	09-07-2008 Change of BN: 24.09.2008	Rs.10000/- dated 26.08.2013 Rs. 10000/- dated 09.07.2018 Dy. No. 1268 dated 13.01.2023 Rs.20000/- dated 10.01.2023 (Slip No.519433822592) Rs. 20000/- (Slip No.3268324595)	Renewal is granted w.e.f 09.08.2018 to 08.08.2023
13.	049286	Sterifluid- Peads Infusion Each 100ml Contains Dextrose Monohydrate eq. to Anhydrous Dextrose4.3gm Sodium Chloride0.18gm (B.P Specs)	09-07-2008 Change of BN: 24.09.2008	Rs.10000/- dated 26.08.2013 Rs. 10000/- dated 09.07.2018 Dy. No. 1268 dated 13.01.2023 Rs.20000/- dated 10.01.2023 (Slip No.7627840088) Rs. 20000/- (Slip No.0174775744)	Renewal is granted w.e.f 09.08.2018 to 08.08.2023
14.	052739	Sterifulid-RL Infusion Each 100ml contains: Sodium Lactate0.32gm Calcium Chloride Di- hydrate0.027gm Potassium Chloride0.04gm Sodium Chloride0.60gm (BP Specifications)	04-11-2008 Correction of formulation dated 06.08.2009	Rs.10000/- dated 26.08.2013 Rs.10000/- dated 18.11.2018 Dy. No. 1268 dated 13.01.2023 Rs.20000/- dated 10.01.2023 (Slip No.79540458)	Renewal is granted w.e.f 04.11.2018 to 03.11.2023
15.	052740	Sterifulid-RLD Infusion Each 100ml contains: Sodium Lactate0.31gm Calcium Chloride Di- hydrate0.027gm Potassium Chloride0.04gm Sodium Chloride0.60gm Dextrose Anhydrous5.0gm (BP Specifications)	04-11-2008	Rs.10000/- dated 26.08.2013 Rs.10000/- dated 18.11.2018 Dy. No. 1268 dated 13.01.2023 Rs.20000/- dated 10.01.2023 (Slip No.11307988)	Renewal is granted w.e.f 04.11.2018 to 03.11.2023
16.	051074	Sterifulid-NS Infusion Each 100ml contains: Sodium Chloride0.9gm (BP Specifications)	20.08.2008	Rs.10000/- dated 26.08.2013 Rs.10000/- dated 09.07.2018	Renewal is granted w.e.f 20.08.2018 to 19.08.2023

		No.8203937070)	
Sterisol-DS Infusion Each 100ml contains Dextrose Monohydrate eq to or Anhydrous Dextrose5.0gm Sodium Chloride0.9gm (BP Specifications) d is mentioned against each case.	01.08.2008	Rs.10000/- dated 26.08.2013 Rs.10000/- dated 09.07.2018 Dy. No. 1268 dated 13.01.2023 Rs.20000/- dated 10.01.2023 (Slip No.74906660)	Renewal is granted w.e.f 01.08.2018 to 31.07.2023

Additional Agenda of Import & Vet-I Section

Case No. 01: Registration of Drugs under the Drugs Act, 1976-Virtual Inspection Reports of Manufacturer Abroad.

Following biological product approved in 321st meeting of Registration Board subject to inspection of manufacturer abroad as per import policy.

S.	Name of Importer/	Name of Drug	Panel of Inspector(s)/
No.	Manufacturer & meeting	&Composition	Date of inspection
	number		
1.	M/s. Brand Station,	Yevac ND vaccine 500ml	(i)Mr. Zafar Minhas, Deputy
	69 Wocland Villas Lahore,	Each dose (0.5ml)	Director (NCLB), DRAP,
	Near Raiwind Road,	contains:-	Islamabad.
	Lahore./	Newcastle Disease Virus	(ii)Sadia Mehvish, Federal
	Manufacturer:	Strain Lasota ≥10 ^{8.1} EID ₅₀	Inspector of Drugs, DRAP,
	M/s. Yebio Bioengineering	before inactivation	Islamabad.
	Co., Ltd Adress: No.260		12-12-2022
	Heyuan Road Hongdao,		&
	Qingdao, China.		21-12-2022

Accordingly, an inspection was carried out by inspection panel dated 12-12-2022 & 21-12-2022 and final remarks of the panel are as under:-

Conclusion:-

The proceedings of the virtual inspection were adversely influenced by a slew of factors summarized below:

- (a) Lack of provision for appropriate tools like cameras, bore scopes, fiberscope etc. By the manufacturer to carry out virtual inspection.
- (b) Lack of provision of internet inside the production facility due to which production area could not be inspected.
- (c) The videos of production area provided by the manufacturer were devoid of description, voiceovers, steps by step explanation of manufacturing process as well as the visuals of machinery in operation.
- (d) Lack of readily available documents for review in English language with notarization or Embassy verification.
- (e) Inadequacy of provided documents & videos as discussed in detail above.
- (f) Non availability of key documents in English language lie veterinary Chinese Pharmacopoeia & Chinese guidelines from an independent source.
- (g) Non compliance of sterile area monitoring practices & their frequencies in accordance with internationally accepted Guidelines.
- (h) Lack of clarification regarding the equivalence of Chinese GMP standards with International

Guidelines & of Chines Veterinary Pharmacopeia with official books (BP), USP etc.) as mentioned in the Drugs Act, 1976 & DRAP Act, 2012.

Considering the facts mentioned above, the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, the panel reached the conclusion that since manufacturing/production facility of the firm could not be viewed combined with deficiencies in the provided documents, it is not possible to ascertain basic vaccine manufacturing system or its compliance with GMP. It is therefore, strongly recommended that on-site inspection of the firm should be carried out before of registration of applied product i.e Yevac ND vaccine and the firm should be compelled/obligated to main & keep an English translation of relevant readily available for review on request.

Decision: Registration Board deliberated the matter and decided to remand back the case to inspecting panel for clear and candid recommendations. The division shall process the case before issuance of minutes of the meeting.

Miscellaneous Decision:

Registration Board while considering the registration applications decided to refer following points to QA& LT Division:

- GMP inspection of the new Manufacturing units must be carried out at least within a year of grant of the drug product registrations.
- During routine inspections being conducted for the sake of GMP or grant of renewal of DML, the panel shall also verify the product development and stability studies data submitted by the firm along with their registration applications.

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